Exhibit L

Page 498 CAUSE NO. 2012-CI-18690 JENNIFER RAMIREZ F/K/A JENNIFER) IN THE DISTRICT COURT GALINDO, Plaintiff,) 438th JUDICIAL DISTRICT vs. CESAR REYES, JOHNSON & JOHNSON,) INC., AND ETHICON, INC., Defendants.) BEXAR COUNTY, TEXAS VOLUME II MARCH 31, 2016 Videotaped deposition of PEGGY PENCE, Ph.D., Volume II, held in the offices of Lopez McHugh, LLP, 100 Bayview Circle, Suite 5600, Newport

GOLKOW TECHNOLOGIES, INC. 877.370.3377 ph | 917.591.5672 fax deps@golkow.com

Beach, California, commencing at 10:16 A.M., on the

above date before Pamela Cotten, CSR, RDR, Certified

Realtime Reporter, Certificate No. 4497.

	Page 499	Page 50
1	APPEARANCES:	1 EXHIBITS
2		(Continued)
3	EDEESE & COSS	2 2 Providence Providence Provi
4	FREESE & GOSS BY: TIM K. GOSS, ESQUIRE	3 Deposition Description Page 4 Exhibit 52 Printout of Slide Titled 530
_	YVETTE DIAZ, ESQUIRE	"Warnings & Precautions,"
5	Suite 200	5 One Page
6	3031 Allen Street Dallas, Texas 75204	6 Exhibit 53 Printout of Slide Titled 534
0	(214) 761-6610	"Risk Known by Ethicon at the Time of the TVT-O Launch
7	Fax - (214) 761-6688	Not in the TVT-O IFU,"
0	tim@freeseandgoss.com	8 Six Pages
8	yvette@freeseandgoss.com Counsel for the Plaintiff	9 Exhibit 54 Excerpt from 2010 TVT-O IFU, 547
9	Counsel for the Figure	Warnings & Precautions, 10 One Page
10	DAVIS, CEDILLO & MENDOZA	11 Exhibit 55 2010 TVT-O IFU re Adverse 547
11	BRIAN L. LEWIS, ESQUIRE	Reactions and Reactions, One
11	McCombs Plaza, Suite 500 755 Mulberry Avenue	12 Page
12	San Antonio, Texas 78212	13 Exhibit 56 1/8/14 Deposition of Thomas 557 Barbolt
	(210) 822-6666	14
13	Fax - (210) 822-1151 blewis@dcm.com	Exhibit 57 Printout of Slide Titled 558
14	Counsel for Johnson & Johnson	15 "Ethicon Scientist Thomas
15		Barbolt," One Page
	SCOTT, CLAWATER & HOUSTON, LLP	Exhibit 58 9/11/13 Deposition of David 561
16	CAROL Y. VERBEEK, ESQUIRE Suite 500	17 Robinson, Volume III
17	2727 Allen Parkway	18 Exhibit 59 Printout of Slide Titled 562
	Houston, Texas 77019	"Ethicon Medical Director
18	(713) 650-6600 Fax - (713) 650-1720	19 David Robinson," One Page 20 Exhibit 60 1/14/14 Deposition of Piet 564
19	cverbeek@schlawyers.com	Hinoul, Volume 4
	Counsel for Dr. Cesar Reyes	21
20		Exhibit 61 Printout of Slide Titled 565 22 "Ethicon Medical Director
21	ALSO PRESENT:	Piet Hinoul," One Page
22	ALDO I REDEIVI.	23
	JOHN SISSON, Videographer	Exhibit 62 Printout of Slide Titled 567
23 24		24 "Ethicon Medical Director Piet Hinoul," One Page
25		25
	Page 500	Page 50
1	_	Page 50
1 2	Page 500	
1 2 3	INDEX	Page 50 1 EXHIBITS (Continued)
2	_	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page
2 3	INDEX Witness: PEGGY PENCE, PhD (Volume II)	Page 50 1 EXHIBITS (Continued)
2 3 4 5 6	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page
2 3 4 5 6 7	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575
2 3 4 5 6 7 8	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and
2 3 4 5 6 7 8 9	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS 506	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575
2 3 4 5 6 7 8 9	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS 506	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 - 834
2 3 4 5 6 7 8 9 10	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS 506 EXHIBITS Deposition Description Page	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581
2 3 4 5 6 7 8 9	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS 506 EXHIBITS Deposition Description Page Exhibit 10A Gynecare TVT Obturator 522	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 - 834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free
2 3 4 5 6 7 8 9 10 11	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-0, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 - 834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse
2 3 4 5 6 7 8 9 10	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS 506 EXHIBITS Deposition Description Page Exhibit 10A Gynecare TVT Obturator 522	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010),"
2 3 4 5 6 7 8 9 10 11	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 - 834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page
2 3 4 5 6 7 8 9 10 11 12	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010),"
2 3 4 5 6 7 8 9 10 11 12	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 - 834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 "Ethicon Tension-Free
2 3 4 5 6 7 8 9 10 11 12 13 14	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 - 834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 "Ethicon Tension-Free Vaginal Tape Obturator MDRs:
2 3 4 5 6 7 8 9 10 11 12 13 14 15	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported
2 3 4 5 6 7 8 9 10 11 12 13 14	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011),"
2 3 4 5 6 7 8 9 10 11 12 13 14 15	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 13 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 14 Most Commonly Reported Adverse Events (2004-2011)," One Page 15 One Page 16 Exhibit 67 Printout of Slide Titled 585
2 3 4 5 6 7 8 9 10 11 12 13 14 15	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 13 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 15 Exhibit 67 Printout of Slide Titled 585 "Ethicon Tension-Free
2 3 4 5 6 7 8 9 10 11 12 13 14 15	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 13 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: 14 Most Commonly Reported Adverse Events (2004-2011)," One Page 15 Exhibit 67 Printout of Slide Titled 585 "Ethicon Tension-Free
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 13 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 15 Exhibit 67 Printout of Slide Titled 585 "Ethicon Tension-Free
2 3 4 5 6 7 8 9 10 11 12 13 14 15	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: 14 Most Commonly Reported Adverse Events (2004-2011)," One Page 16 Exhibit 67 Printout of Slide Titled 585 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011) By Year," One Page
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 - 834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 13 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 16 Exhibit 67 Printout of Slide Titled 585 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011) By Year," One Page
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 14 Most Commonly Reported Adverse Events (2004-2011)," One Page 15 One Page 16 Exhibit 67 Printout of Slide Titled 585 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011) By Year," One Page 19 Exhibit 68 6/26/08 GHTF Final Document, 590
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 16 Exhibit 67 Printout of Slide Titled 585 "Ethicon Tension-Free 17 Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 18 Adverse Events (2004-2011) By Year," One Page 19 Exhibit 68 6/26/08 GHTF Final Document, 590 Title: Principles of
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 3 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director 5 Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 - 834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 13 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 16 Exhibit 67 Printout of Slide Titled 585 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011) By Year," One Page 19 Exhibit 68 6/26/08 GHTF Final Document, 590 Title: Principles of Conformity Assessment for Medical Devices, 32 Pages
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-0, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 15 One Page 16 Exhibit 67 Printout of Slide Titled 585 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 17 One Page 18 Adverse Events (2004-2011) By Year," One Page 19 Exhibit 68 6/26/08 GHTF Final Document, 590 Title: Principles of Conformity Assessment for Medical Devices, 32 Pages 22 Exhibit 69 Printout of Slide Titled 595
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-O, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 8 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 16 Exhibit 67 Printout of Slide Titled 585 "Ethicon Tension-Free 17 Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011) By Year," One Page 19 Exhibit 68 6/26/08 GHTF Final Document, 590 Title: Principles of Conformity Assessment for Medical Devices, 32 Pages 12 Exhibit 69 Printout of Slide Titled 595 "Ethicon Medical Director
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	INDEX Witness: PEGGY PENCE, PhD (Volume II) Examination: Page BY MR. GOSS	Page 50 1 EXHIBITS (Continued) 2 Deposition Description Page 4 Exhibit 63 Printout of Slide Titled 569 "Ethicon Medical Director Piet Hinoul," One Page 6 Exhibit 64 Issue Report TVT-0, Open 575 Date Between 01-Jan-2010 and 7 31-Dec-2010 Bates Nos. ETH.MESH.02656825 -834 9 Exhibit 65 Printout of Slide Titled 581 "Ethicon Tension-Free 10 Vaginal tape MDRs: Most Commonly Reported Adverse 11 Events (1999-2010)," One Page 12 Exhibit 66 Printout of Slide Titled 581 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 15 One Page 16 Exhibit 67 Printout of Slide Titled 585 "Ethicon Tension-Free Vaginal Tape Obturator MDRs: Most Commonly Reported Adverse Events (2004-2011)," One Page 17 One Page 18 Adverse Events (2004-2011) By Year," One Page 19 Exhibit 68 6/26/08 GHTF Final Document, 590 Title: Principles of Conformity Assessment for Medical Devices, 32 Pages 22 Exhibit 69 Printout of Slide Titled 595

2 (Pages 499 to 502)

Page 503 Page 505 NEWPORT BEACH, CALIFORNIA - THURSDAY, MARCH 31, 2016 1 tomorrow in the presiding court. 2 10:16 A.M. 2 With that, we will continue to proceed with 3 VIDEO OPERATOR SISSON: Good morning. We are now 3 this deposition. MR. GOSS: Okay. Obviously, that's all for 4 on the record. My name is John Sisson. I'm the 4 5 videographer for Golkow Technologies. 5 discussion tomorrow, I guess. 6 Today is March 31, 2016. It is now 10:16 in 6 7 7 the morning **EXAMINATION** 8 8 This video deposition is being held in Newport BY MR. GOSS: 9 Beach, California, in the matter of Ramirez versus 9 Q Okay. Good morning, Dr. Pence. 10 Ethicon, Incorporated, et al., for District Court, 10 A Good morning, Mr. Goss. 11 438th Judicial District, Bexar County, Texas. Today we 11 Q And you understand this is the continuation of 12 are taking Volume 2 in the deposition of Peggy Pence. 12 your deposition testimony? 13 Counsel, will you please now identify 13 A Yes, I do. 14 yourselves for the record. 14 Q Okay. I want to -- and just for the record, 15 MR. GOSS: Tim Goss and Yvette Diaz for plaintiff. 15 we are waiting for some of the exhibits -- well, all VIDEO OPERATOR SISSON: On the phone? 16 16 the exhibits that were used in your deposition last 17 MR. LEWIS: Brian Lewis for Ethicon and Johnson & 17 week. They didn't make it over by 10:00 from the court 18 Johnson. 18 reporter. I understand the court reporter firm is 19 MS. VERBEEK: Carol Verbeek for Dr. Cesar Reyes. 19 going to try to get them here by 10:30. It is now 20 VIDEO OPERATOR SISSON: Thanks very much. 20 10:15 or -16 or so. So I'm going to start a little --21 Will our court reporter please now -- reswear 21 a place that might be a little awkward in my outline, 22 the witness. By the way, our court reporter today is 22 then we will pick back up to where we stopped last 23 Pam Cotten, my error. 23 time. Okay? 24 /// 24 A Sounds fine. 25 25 VIDEO OPERATOR SISSON: If you could pause for a Page 504 Page 506 PEGGY PENCE, PhD. RAC, FRAPS. 1 second. 10:19, we are off the record. 1 2 called as a witness, and having been first duly sworn 2 (Off-the-record discussion.) 3 3 VIDEO OPERATOR SISSON: At 10:20, we are back on by the Certified Shorthand Reporter, was examined and 4 testified as follows: 4 the record. 5 5 MR. GOSS: Let me also add that, out of fairness, 6 MR. GOSS: We are here for the continuation of 6 what I am trying to do this morning is I have forwarded 7 7 Dr. Pence's deposition, but before we do that I to -- as soon as I got the email for the counsel that 8 8 understand that Ethicon's lawyer, Brian Lewis, wants to would be defending the depositions for the defendants, 9 9 make a statement for the record. I have forwarded a group of slides and some other 10 10 MR. LEWIS: Yes. This is Brian Lewis. I'm an things that I wanted to make sure that they had before 11 11 attorney for Ethicon and Johnson & Johnson. I'm with we got started so as to not be at a disadvantage. 12 12 the law firm of Davis, Cedillo & Mendoza in San I have also informed counsel that if during 13 13 Antonio, Texas. I just want to note for the record the deposition there is something that I'm using that 14 14 you need to see, I will endeavor to get it emailed to that by our appearance here today in the continuation of Dr. Pence's second deposition, we are not waiving 15 15 you as quickly as possible. I think I can do it fairly 16 16 quickly because I think we have got most of the the objections made by Ethicon's counsel, 17 17 Ms. Sutherland, during the initial deposition as to the exhibits handy on -- I don't know a lot about 18 18 continuation of this deposition, the nature of the computers, but on a hard drive or whatever it is 19 19 called. deposition and trial deposition, and also the notice 20 20 for the follow-up destination scheduled for today. We Okay. With that, I'm going to go forward. I 21 21 are also not waiving any of the objections and assume, as I understand it, the lawyers on the phone, 22 22 arguments that are also set forth in the motion that we you have received my first group of documents that I've 23 23 emailed to you; is that right? filed on the 29th of March for a protective order and 24 MR. LEWIS: That's correct. 24 for a motion to compel additional time to depose 25 plaintiff's expert. That motion is set for hearing 25 MR. GOSS: Okay. Carol?

	Page 507		Page 509
1	MS. DIAZ: Oh, sorry. You were on mute. That's	1	Is that a transcript that you reviewed in your
2	correct.	2	investigation in this case?
3	MR. GOSS: Okay. All right. With that, I'll	3	A Yes, it is.
4	proceed.	4	Q And did the testimony in that transcript form
5	BY MR. GOSS:	5	the basis in whole or in part in any of your opinions
6	Q Dr. Pence, I would like to talk to you a	6	in this case?
7	little bit about heavyweight mesh. Okay?	7	A Yes.
8	A Okay.	8	Q Okay. And to back up a little bit, is
9	Q You understand what I'm talking about when I	9	Dr. Holste the one whose testimony you said supports
10	say "heavyweight mesh"?	10	your understanding that it was heavyweight mesh?
11	A Yes, I do.	11	A Yes.
12	Q In your investigation of Ethicon, did you	12	Q In that regard, I'm going to refer you to the
13	review any testimony or internal documents regarding	13	July 29th transcript at page 40, lines 12 through 15,
14	heavyweight mesh versus lightweight mesh?	14	and ask that you read those lines, 12 through 15,
15	A Yes, I did.	15	question and answer.
16	Q Did you review any testimony from Ethicon as	16	"Question: And Prolene,
17	to whether the mesh in the Prolene mesh, or TVT-O,	17	old-construction mesh at 100 to
18	that Jennifer Ramirez got, whether that mesh was	18	110 grams per meter squared is
19	heavyweight or lightweight?	19	considered a heavyweight mesh; correct?
20	A Yes, I did.	20	"Answer: Yes."
21	Q And what did you review, what testimony?	21	Q And is that the testimony you relied upon for
22	A I reviewed the testimony, for example, of	22	support of your opinion it's heavyweight mesh?
23	Dr. Joerg Holste, who is in charge of preclinical	23	A Yes.
24	development, has been with the company for over 30	24	Q Do you know whether or not the Prolene
25	years, and which he testified that the Prolene mesh is	25	old-construction mesh that's referenced in the
	Page 508		Page 510
1	heavyweight mesh.	1	testimony that you just read is the same mesh that is
2	(The documents referenced below	2	used in the TVT-O?
3	were marked Deposition Exhibits 47 and	3	A Yes.
4	48 for identification and are appended	4	Q Is it?
5	hereto.)	5	A Yes, it is.
6	BY MR. GOSS:	6	Q In your investigation, did you see there any
7	Q Okay. I'm going to hand you what's been	7	discussion as to any of the risks that may be created
8	marked as your Exhibits 47 and 48. I actually probably	8	by heavyweight mesh?
9	did this backwards, now that I look at it, but is	9	A Yes.
10	Exhibit 48 a transcript it appears to be a	10	Q And did you review any testimony in that
11	transcript dated July 29th, 2013, given in the MDL in	11	regard?
12	West Virginia for the videotaped deposition of	12	A Yes.
1		1 0	
13	Dr. Holste.	13	Q And whose testimony did you review?
13 14	Is that a transcript that you reviewed in your	13 14	A I read, for example, Dr. Holste's testimony.
	Is that a transcript that you reviewed in your investigation in this case?	14 15	A I read, for example, Dr. Holste's testimony. He did testify about that.
14 15 16	Is that a transcript that you reviewed in your investigation in this case? A Yes, it is.	14 15 16	A I read, for example, Dr. Holste's testimony. He did testify about that. Q Okay. I would like to refer you to I've
14 15	Is that a transcript that you reviewed in your investigation in this case? A Yes, it is. Q Is that a transcript that you relied on in	14 15 16 17	A I read, for example, Dr. Holste's testimony. He did testify about that. Q Okay. I would like to refer you to I've got an excerpt here for you refer you to pages 51
14 15 16 17 18	Is that a transcript that you reviewed in your investigation in this case? A Yes, it is. Q Is that a transcript that you relied on in whole or in part for some of your opinions in this	14 15 16 17 18	A I read, for example, Dr. Holste's testimony. He did testify about that. Q Okay. I would like to refer you to I've got an excerpt here for you refer you to pages 51 through 53 of the July 29th testimony. Is any of that
14 15 16 17 18 19	Is that a transcript that you reviewed in your investigation in this case? A Yes, it is. Q Is that a transcript that you relied on in whole or in part for some of your opinions in this case?	14 15 16 17 18 19	A I read, for example, Dr. Holste's testimony. He did testify about that. Q Okay. I would like to refer you to I've got an excerpt here for you refer you to pages 51 through 53 of the July 29th testimony. Is any of that testimony anything that you relied upon in forming you
14 15 16 17 18	Is that a transcript that you reviewed in your investigation in this case? A Yes, it is. Q Is that a transcript that you relied on in whole or in part for some of your opinions in this case? A Yes.	14 15 16 17 18 19 20	A I read, for example, Dr. Holste's testimony. He did testify about that. Q Okay. I would like to refer you to I've got an excerpt here for you refer you to pages 51 through 53 of the July 29th testimony. Is any of that testimony anything that you relied upon in forming you opinions in this case?
14 15 16 17 18 19 20 21	Is that a transcript that you reviewed in your investigation in this case? A Yes, it is. Q Is that a transcript that you relied on in whole or in part for some of your opinions in this case? A Yes. Q Okay. And I'm going to ask you the same	14 15 16 17 18 19 20 21	A I read, for example, Dr. Holste's testimony. He did testify about that. Q Okay. I would like to refer you to I've got an excerpt here for you refer you to pages 51 through 53 of the July 29th testimony. Is any of that testimony anything that you relied upon in forming you opinions in this case? A Yes, it is.
14 15 16 17 18 19 20 21 22	Is that a transcript that you reviewed in your investigation in this case? A Yes, it is. Q Is that a transcript that you relied on in whole or in part for some of your opinions in this case? A Yes. Q Okay. And I'm going to ask you the same questions regarding Exhibit 47, which on its face	14 15 16 17 18 19 20 21	A I read, for example, Dr. Holste's testimony. He did testify about that. Q Okay. I would like to refer you to I've got an excerpt here for you refer you to pages 51 through 53 of the July 29th testimony. Is any of that testimony anything that you relied upon in forming you opinions in this case? A Yes, it is. Q And on page 51 at line 25, it begins with a
14 15 16 17 18 19 20 21	Is that a transcript that you reviewed in your investigation in this case? A Yes, it is. Q Is that a transcript that you relied on in whole or in part for some of your opinions in this case? A Yes. Q Okay. And I'm going to ask you the same questions regarding Exhibit 47, which on its face reflects that it is Volume II of a deposition	14 15 16 17 18 19 20 21 22 23	A I read, for example, Dr. Holste's testimony. He did testify about that. Q Okay. I would like to refer you to I've got an excerpt here for you refer you to pages 51 through 53 of the July 29th testimony. Is any of that testimony anything that you relied upon in forming you opinions in this case? A Yes, it is. Q And on page 51 at line 25, it begins with a question.
14 15 16 17 18 19 20 21 22	Is that a transcript that you reviewed in your investigation in this case? A Yes, it is. Q Is that a transcript that you relied on in whole or in part for some of your opinions in this case? A Yes. Q Okay. And I'm going to ask you the same questions regarding Exhibit 47, which on its face	14 15 16 17 18 19 20 21	A I read, for example, Dr. Holste's testimony. He did testify about that. Q Okay. I would like to refer you to I've got an excerpt here for you refer you to pages 51 through 53 of the July 29th testimony. Is any of that testimony anything that you relied upon in forming you opinions in this case? A Yes, it is. Q And on page 51 at line 25, it begins with a

4 (Pages 507 to 510)

	Page 511		Page 513
1	Ethicon developed a lighter-weight	1	A If it impacts safety and performance, yes,
2	large-pore mesh was so that less foreign	2	that would be appropriate.
3	material would be left behind in the	3	Q Based upon Dr. Holste's testimony, would it
4	tissue; correct?	4	impact safety or performance?
5	"Answer: That is correct, yes,	5	A Yes.
6	"Question: Because the more	6	Q Do you know first of all, did you review in
7	foreign material that's left in the	7	your investigation of Ethicon's files any documents
8	tissue, the greater the foreign-body	8	that reflected whether or not Ethicon had
9		9	lighter-weight meshes than Prolene mesh prior to 2010?
	reaction; correct?"	10	A Yes.
10	Some objections	11	
11	"Answer: That is correct, yes.		Q And what did your investigation determine?
12	"And if more foreign body that's in	12	A Yes, the company did have other meshes that
13	the body that creates a greater	13	were lighter weight.
14	foreign-body reaction also can create a	14	Q What were those some of those other meshes?
15	greater inflammatory reaction; correct?	15	A ULTRAPRO, Vypro, for example.
16	"Answer: Yes.	16	Q Okay. Were any of those meshes that were
17	"And if you have more foreign	17	lighter-weight meshes being used?
18	material causing a greater inflammatory	18	A In other products, yes.
19	reaction, it can cause complications in	19	Q Did you see anything in your investigation,
20	patients; correct?	20	any documents or testimony in your investigation as to
21	"That can be assumed, yes.	21	why as to why a lighter-weight mesh could not have
22	"Question: One of the problems	22	been used in the TVT-O?
23	that a greater inflammatory reaction can	23	A No.
24	cause in the human tissue to a foreign	24	MR. LEWIS: Objection. Form.
25	body like a polypropylene mesh implant	25	THE WITNESS: The company would have obviously h
	Page 512		Page 514
1	is if there can be more contraction,	1	to do the appropriate development work, but, no, they
2	sometimes known as mesh shrinkage;	2	had the mesh available and could have done the
3	correct?	3	development work.
4	"Answer: Yes."	4	BY MR. GOSS:
5	Did I read that correctly?	5	Q Did you see whether or not the company did an
6	A Yes, you did.	6	development work or clinical testing of any
7	Q And what did you rely upon, with respect to	7	lighter-weight meshes for the TVT-O?
8	that testimony, for your opinion, if any?	8	A No
9	A With regard to the fact that the	9	Q Okay. Would a reasonable and prudent
	9	10	manufacturer have done those tests?
10	heavier-weight mesh does result in a greater		
11	foreign-body reaction, greater inflammatory reaction,	11	A Yes.
12	and that greater inflammatory reaction, as is noted in	12	Q Would those types of tests be mandated by the
13	the testimony and this is also reported in the	13	Global Harmonization Task Force guidelines, for
14	literature and other places as well, documentation and	14	example, the clinical evaluation document that we have
15	testimony that I reviewed that additional greater	15	looked at?
16	inflammatory reaction can result in more more of	16	A In terms of providing a safer alternative, if
17	a of a contraction. The tissue around the mesh can	17	there is a safer alternative available, it would be
18	compress the mesh and cause a contraction. That can	18	appropriate for a company to if there is a problem
19	cause pain. It could cause other types of	19	with safety and performance related to the material and
20	complications as well.	20	the design of the product, it would be appropriate to
21	Q Does the 2010 IFU reflect whether the mesh is	21	implement an improved design, yes
			O A - 1 T -1 - 1 -1 -1 -1
22	heavyweight or lightweight?	22	Q And I believe we looked at
	heavyweight or lightweight? A No, it does not.	22 23	MR. LEWIS: Objection. Nonresponsive.
22			-

5 (Pages 511 to 514)

	Page 515		Page 517
1	the first day of your deposition, from the Global	1	BY MR. GOSS:
2	Harmonization Task Force entitled Essential Principles	2	Q Okay. I'm going to as I mentioned before
3	of Safety in Performance of Medical Devices.	3	we started the deposition, the exhibits aren't here yet
4	Do you recall that?	4	from your prior deposition, so I'm going to mark
5	A Yes, I do.	5	another one of the Global Harmonization Task Force
6	Q Was there anything in that guideline which	6	documents that we used last deposition as one entitled
7	I understand you said were standards in the industry;	7	Essential Principles of Safety and Performance of
8	is that correct?	8	Medical Devices.
9	A Right.	9	Do you remember that one?
10	Q Is there anything in that guideline that would	10	A Yes.
11	require a manufacturer to eliminate risk as reasonably	11	Q Dated May 20th, 2005, and I would like I'm
12	practical?	12	marking this as Exhibit 49. I'll hand it to you.
13	A Yes. One is the global standard for medical	13	I'll represent to you that I have highlighted
14	device development requires that safety and performance	14	on page 8 and 9 for future use as a potential slide
15	information related to a product is fed back into the	15	some language I want to talk with you about.
16	risk analysis so that there is that the benefit	16	But is Exhibit 49 the document one of the
17	that there's always a favorable benefit-to-risk ratio	17	documents that you have discussed in your deposition
18	and that any risks are acceptable, and if one has to	18	last week?
19	mitigate risk when one learns of safety issues. And	19	A Yes, it is. It is one of the guidance
20	the discussion that we are having, one of the ways to	20	documents for GHTF, and it is through a number of
21	mitigate risk with TVT-O would have been to implement	a 21	guidance documents that GHTF implemented or developed
22	lighter-weight product, lighter-weight mesh.	22	that global model for medical device development that I
23	MR. LEWIS: Objection. Nonresponsive.	23	was mentioning.
24	BY MR. GOSS:	24	Q Okay. And if you would go to page is it 8?
25	Q I want to just reference you back to the	25	A Eight.
	Page 516		Page 518
1	Global Harmonization Task Force document, just so we	1	Q Go to page 8, section 5.2 of page 8, where it
2	can reorient ourselves. Can you explain what the	2	picks up with, "The manufacturer should apply the
3	Global Harmonization	3	following principles in the priority order listed," and
4	A Certainly.	4	it says, the first bullet point on page 8:
5	Q Task Force various guidelines are, what	5	"Identify known or foreseeable
6	that is and what the various guidelines are?	6	
7	A V Th-Cl-b-l H		hazards and estimate the associated risk
	A Yes. The Global Harmonization Task Force,	7	hazards and estimate the associated risk arising from the intended use of
8	often referred to for short as GHTF, was implemented in	7	
8 9	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It	7 n 8 9	arising from the intended use of
	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite	7 n 8 9	arising from the intended use of foreseeable misuse."
9	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada,	7 n 8 9 d 10 11	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently
9 10 11 12	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the	7 n 8 9 d 10 11 12	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture."
9 10 11 12 13	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry	7 n 8 9 d 10 11 12	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point:
9 10 11 12 13 14	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these	7 n 8 9 d 10 11 12 13	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point: "Reduce as far as reasonably
9 10 11 12 13 14 15	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these various countries, and some additional bodies and	7 1 8 9 1 11 12 13 14	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point: "Reduce as far as reasonably practical the remaining risk by taking
9 10 11 12 13 14 15	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these various countries, and some additional bodies and entities involved in medical device development later	7 1 8 9 1 10 11 12 13 14 15 16	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point: "Reduce as far as reasonably practical the remaining risk by taking adequate protection measures, including
9 10 11 12 13 14 15 16	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these various countries, and some additional bodies and entities involved in medical device development later entered the group as well.	7 1 8 9 10 11 12 13 14 15 16 17	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point: "Reduce as far as reasonably practical the remaining risk by taking adequate protection measures, including alarms."
9 10 11 12 13 14 15 16 17	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these various countries, and some additional bodies and entities involved in medical device development later entered the group as well. The idea was to develop a global model for the	7 1 8 9 d 10 11 12 13 14 15 16 17 18	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point: "Reduce as far as reasonably practical the remaining risk by taking adequate protection measures, including alarms." And the last point:
9 10 11 12 13 14 15 16 17 18	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these various countries, and some additional bodies and entities involved in medical device development later entered the group as well. The idea was to develop a global model for the development of medical devices worldwide, essentially	7 1 8 9 d 10 11 12 13 14 15 16 17 18 a 19	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point: "Reduce as far as reasonably practical the remaining risk by taking adequate protection measures, including alarms." And the last point: "Inform users of any residual risk."
9 10 11 12 13 14 15 16 17 18 19 20	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these various countries, and some additional bodies and entities involved in medical device development later entered the group as well. The idea was to develop a global model for the development of medical devices worldwide, essentially global standard to enhance patient safety and bringing	7 1 8 9 d 10 11 12 13 14 15 16 17 18 a 19 20	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point: "Reduce as far as reasonably practical the remaining risk by taking adequate protection measures, including alarms." And the last point: "Inform users of any residual risk." Did I read that right?
9 10 11 12 13 14 15 16 17 18 19 20 21	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these various countries, and some additional bodies and entities involved in medical device development later entered the group as well. The idea was to develop a global model for the development of medical devices worldwide, essentially global standard to enhance patient safety and bringing innovative new medical devices to market efficiently.	7 1 8 9 d 10 11 12 13 14 15 16 17 18 a 19 20 21	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point: "Reduce as far as reasonably practical the remaining risk by taking adequate protection measures, including alarms." And the last point: "Inform users of any residual risk." Did I read that right? A Yes, you did.
9 10 11 12 13 14 15 16 17 18 19 20 21	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these various countries, and some additional bodies and entities involved in medical device development later entered the group as well. The idea was to develop a global model for the development of medical devices worldwide, essentially global standard to enhance patient safety and bringing innovative new medical devices to market efficiently. (The document referenced below was	7 8 9 d 10 11 12 13 14 15 16 17 18 a 19 20 21 22	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point: "Reduce as far as reasonably practical the remaining risk by taking adequate protection measures, including alarms." And the last point: "Inform users of any residual risk." Did I read that right? A Yes, you did. Q Okay. Do any of these apply to your testimony
9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these various countries, and some additional bodies and entities involved in medical device development later entered the group as well. The idea was to develop a global model for the development of medical devices worldwide, essentially global standard to enhance patient safety and bringing innovative new medical devices to market efficiently. (The document referenced below was marked Deposition Exhibit 49 for	7 8 9 d 10 11 12 13 14 15 16 17 18 a 19 20 21 22 23	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point: "Reduce as far as reasonably practical the remaining risk by taking adequate protection measures, including alarms." And the last point: "Inform users of any residual risk." Did I read that right? A Yes, you did. Q Okay. Do any of these apply to your testimony relating to heavyweight and lightweight meshes?
9 10 11 12 13 14 15 16 17 18 19 20 21 22	often referred to for short as GHTF, was implemented in 1992 and had a duration of approximately 20 years. It had five founding members, one of which was the Unite States as well as Europe, Japan, Australia, and Canada, if I recall correctly as I sit here today. And the purpose of that organization was to bring both industry representatives as well as regulators from these various countries, and some additional bodies and entities involved in medical device development later entered the group as well. The idea was to develop a global model for the development of medical devices worldwide, essentially global standard to enhance patient safety and bringing innovative new medical devices to market efficiently. (The document referenced below was	7 8 9 d 10 11 12 13 14 15 16 17 18 a 19 20 21 22	arising from the intended use of foreseeable misuse." The next bullet point: "Eliminate risk as far as reasonably practical through inherently safe design and manufacture." Third bullet point: "Reduce as far as reasonably practical the remaining risk by taking adequate protection measures, including alarms." And the last point: "Inform users of any residual risk." Did I read that right? A Yes, you did. Q Okay. Do any of these apply to your testimony

6 (Pages 515 to 518)

Page 519 Page 521 1 A For example, "Identify known or foreseeable 1 Do you recognize that document? 2 hazards and estimate the associated risk arising from 2 A Yes, I do. Thank you. 3 the intended use." In terms of the heavyweight mesh 3 Q And there was a little bit of discussion about 4 4 and the fact that, as Dr. Holste testified and as we that last week, as I recall; is that right? 5 5 were just discussing, that the greater -- that the A Yes. To the best of my recollection also, 6 6 heavyweight mesh causes a greater foreign-body yes. 7 reaction, a greater inflammatory reaction, which can 7 Q I'm going to mark a -- what was marked as 8 8 Exhibit 10 was the deposition exhibit for Dr. -- when cause greater contraction and shrinkage which can have 9 complications associated with it, that is relevant to 9 it was used with Dr. Reyes and it only has the English 10 that issue with heavyweight mesh. 10 version of it. Is that right? 11 11 A Yes. Secondly, "Eliminating risk as far as 12 12 reasonably practical through inherently safe design and MR. GOSS: So unless someone objects, just so that 13 manufacture." That goes back to what I was saying a 13 we have a complete IFU in the record, I'm going to mark 14 14 the complete IFU as Exhibit 10A. short while ago, that knowing that lighter-weight mesh 15 15 can reduce the foreign-body -- has the potential to And just for those folks on the phone, all it 16 has done -- all it adds is all the different languages. 16 reduce the foreign-body reaction and inflammatory 17 reaction, therefore, may cause reduced complications. 17 So 10, which we used last week, is the English -- just 18 That would mean that that would be a safer design. So 18 up through the English, and I'm going to mark 10A just 19 19 so we have a complete record. that -- that point goes to --20 20 Q Okay. (The document referenced above was 21 A -- to that. 21 marked Deposition Exhibit 10A for 22 22 Q You are referencing Exhibit 49. And is it identification and is appended hereto.) 23 23 your position these are the written standards in the BY MR. GOSS: 24 industry, some of them? 24 Q Dr. Pence, is Exhibit 10 simply the English 25 25 version taken out of the whole 10A? A Yes. This is the -- this is one of the Page 520 Page 522 guidance documents, a very key document, Essential 1 A Yes. 2 Principles of Safety and Performance, that is part of 2 Q Okay. All right. 3 the global model that has been developed for medical 3 All right. Now, when I retained you in this 4 devices through the work of the Global Harmonization 4 case, was one of the things that I asked you to look at 5 5 the IFU? Task Force. 6 Q Okay. Let's move off that subject. I think 6 A Yes. 7 that we marked the 2010 IFU last time and, again, the 7 Q And I asked you to determine whether or not it exhibits aren't here -- that's them? 8 8 was adequate or inadequate? 9 9 MS. DIAZ: Uh-huh. A That is correct. 10 10 MR. GOSS: I'm told that the exhibits just arrived. Q Did you ever endeavor to do so? 11 A I did. 11 Let me see those. So we now have the exhibits. I see. 12 12 Q All right. Are there professional standards All right. 13 13 So, Ms. Court Reporter, I know that you can't that set forth what should go into an IFU? 14 type and talk at the same time, so what I've got here 14 A Yes, there are. 15 is I've got a set of exhibits that go through 46? 15 Q And are you familiar with those standards? 16 THE REPORTER: Yes. 16 A Yes, I am. 17 17 MR. GOSS: And we just picked up with 47. Okay. Q Just to back up a little bit, explain to the 18 All right. For everybody on the phone, we now have the 18 jury what the IFU is. 19 A The IFU stands for Instructions For Use. It 19 stack of exhibits, and you all should have copies of is the cornerstone of risk management because it is the 20 20 those that were provided during the deposition last 21 week. 21 primary communication between the manufacturer and the 22 22 BY MR. GOSS: user of the device, in this case a surgeon. It 23 Q So, Dr. Pence, I'm going to hand to you -- I'm 23 provides information on the purpose of the device, what 24 24 going to hand you what was marked in your deposition it is to be used for, how -- the patient population, 25 last week, the 2010 IFU for the TVT-O. the types of patients in which it is to be used, how it

	Page 523		Page 525
1	is to be used, the instructions for its use, and, very	1	support of your opinions today?
2	importantly, safety and risk information.	2	A Yes, it is.
3	Q Okay.	3	Q About labeling?
4	A If I might add, the key purpose, it should	4	A Yes.
5	include all information necessary for the safe and	5	Q Did you rely upon anything in the blue book in
6	effective use of the device.	6	support of your opinions today about labeling?
7	Q Is there any debate about that?	7	A Yes, I did.
8	A No.	8	Q Last week we also, I believe, marked and
9	Q We discussed the remember discussions of	9	used see if I can find it here Exhibit 24 and
10	the blue book last week?	10	Exhibit 25. Exhibit 24 being a Global Harmonization
11	A I do.	11	Task Force document regarding Essential Principles of
12	Q I'm going to hand you what has been marked as	; 12	Safety and Performance of Medical Devices and
13	Exhibit 2 and ask you	13	Exhibit 25 being a Global Harmonization Task Force
14	A Thank you.	14	document entitled Clinical Evaluation.
15	Q is that the blue book?	15	Did you rely on Exhibits 24 and 25 in giving
16	A Yes, it is.	16	your in reaching your opinions that you are going to
17	Q Please explain what the blue book is.	17	give today regarding labeling?
18	A This is published by the U.S. Food & Drug	18	A Yes, I did.
19	Administration, the FDA, and in particular it is a	19	Q Okay. All right. What I would like to focus
20	guidance document and it is called Device Labeling	20	on is in the IFU, the Adverse Reaction section and the
21	Guidance, given a number, G91-1, and referred to as a		Precautions and Warnings sections.
22	blue memo.	22	Have you found those?
23	Q Is that a written standard in the industry?	23	A Yes.
24	A Yes, it is.	24	Q All right. I want to visit with you a little
25	///	25	bit about this.
	···		
	Page 524		Page 526
1	Page 524	1	Page 526
1	(The document referenced below was	1	A All right.
2	(The document referenced below was marked Deposition Exhibit 50 for	2	A All right. Q First of all, did you undertake an
2	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.)	2	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not
2 3 4	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS:	2 3 4	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate?
2 3 4 5	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as	2 3 4 5	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did.
2 3 4 5 6	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you	2 3 4 5 6	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts
2 3 4 5 6 7	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another	2 3 4 5 6 7	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you
2 3 4 5 6 7 8	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled	2 3 4 5 6 7 8	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction
2 3 4 5 6 7 8	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005.	2 3 4 5 6 7 8	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate?
2 3 4 5 6 7 8 9	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document?	2 3 4 5 6 7 8 9	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did.
2 3 4 5 6 7 8 9 10	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of	2 3 4 5 6 7 8 9 10 f 11	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion?
2 3 4 5 6 7 8 9 10 11 12	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at	2 3 4 5 6 7 8 9 10 f 11 12	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate.
2 3 4 5 6 7 8 9 10 11 12 13	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination	2 3 4 5 6 7 8 9 10 f 11 12	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the
2 3 4 5 6 7 8 9 10 11 12 13 14	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that	2 3 4 5 6 7 8 9 10 f 11 12 13	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the contraindications and I'm sorry, the Warnings and
2 3 4 5 6 7 8 9 10 11 12 13 14 15	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that means, representatives of manufacturers, and regulators	2 3 4 5 6 7 8 9 10 f 11 12 13 14 15	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the contraindications and I'm sorry, the Warnings and Precautions section, did you reach a conclusion as to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that means, representatives of manufacturers, and regulators from the various countries that I mentioned.	2 3 4 5 6 7 8 9 10 f 11 12 13 14 15 16	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the contraindications and I'm sorry, the Warnings and Precautions section, did you reach a conclusion as to whether or not that section was adequate?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that means, representatives of manufacturers, and regulators from the various countries that I mentioned. And this is one of the guidance documents	2 3 4 5 6 7 8 9 10 f 11 12 13 14 15 16 17	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the contraindications and I'm sorry, the Warnings and Precautions section, did you reach a conclusion as to whether or not that section was adequate? A Yes, I did.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that means, representatives of manufacturers, and regulators from the various countries that I mentioned. And this is one of the guidance documents that was published by GHTF in final form as one of the	2 3 4 5 6 7 8 9 10 f 11 12 13 14 15 16 17 18	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the contraindications and I'm sorry, the Warnings and Precautions section, did you reach a conclusion as to whether or not that section was adequate? A Yes, I did. Q And what was that opinion?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that means, representatives of manufacturers, and regulators from the various countries that I mentioned. And this is one of the guidance documents that was published by GHTF in final form as one of the guidances that is important to the global model for	2 3 4 5 6 7 8 9 10 f 11 12 13 14 15 16 17 18	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the contraindications and I'm sorry, the Warnings and Precautions section, did you reach a conclusion as to whether or not that section was adequate? A Yes, I did. Q And what was that opinion? A That section also is not adequate.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that means, representatives of manufacturers, and regulators from the various countries that I mentioned. And this is one of the guidance documents that was published by GHTF in final form as one of the guidances that is important to the global model for development and marketing of medical devices. And the	2 3 4 5 6 7 8 9 10 f 11 12 13 14 15 16 17 18 19 is 20	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the contraindications and I'm sorry, the Warnings and Precautions section, did you reach a conclusion as to whether or not that section was adequate? A Yes, I did. Q And what was that opinion? A That section also is not adequate. Q Okay. So in your investigation to determine
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that means, representatives of manufacturers, and regulators from the various countries that I mentioned. And this is one of the guidance documents that was published by GHTF in final form as one of the guidances that is important to the global model for development and marketing of medical devices. And the particular one is called Labeling for Medical Devices.	2 3 4 5 6 7 8 9 10 f 11 12 13 14 15 16 17 18 19 is 20 21	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the contraindications and I'm sorry, the Warnings and Precautions section, did you reach a conclusion as to whether or not that section was adequate? A Yes, I did. Q And what was that opinion? A That section also is not adequate. Q Okay. So in your investigation to determine whether or not the Adverse Reaction section, for
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that means, representatives of manufacturers, and regulators from the various countries that I mentioned. And this is one of the guidance documents that was published by GHTF in final form as one of the guidances that is important to the global model for development and marketing of medical devices. And the particular one is called Labeling for Medical Devices. Q Is this a written standard in the industry	2 3 4 5 6 7 8 9 10 f 11 12 13 14 15 16 17 18 19 is 20 21 22	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the contraindications and I'm sorry, the Warnings and Precautions section, did you reach a conclusion as to whether or not that section was adequate? A Yes, I did. Q And what was that opinion? A That section also is not adequate. Q Okay. So in your investigation to determine whether or not the Adverse Reaction section, for example, was adequate, what did you do?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that means, representatives of manufacturers, and regulators from the various countries that I mentioned. And this is one of the guidance documents that was published by GHTF in final form as one of the guidances that is important to the global model for development and marketing of medical devices. And th particular one is called Labeling for Medical Devices. Q Is this a written standard in the industry regarding labeling?	2 3 4 5 6 7 8 9 10 f 11 12 13 14 15 16 17 18 19 is 20 21 22 23	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the contraindications and I'm sorry, the Warnings and Precautions section, did you reach a conclusion as to whether or not that section was adequate? A Yes, I did. Q And what was that opinion? A That section also is not adequate. Q Okay. So in your investigation to determine whether or not the Adverse Reaction section, for example, was adequate, what did you do? A I evaluated a number of documents. Of course,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	(The document referenced below was marked Deposition Exhibit 50 for identification and is appended hereto.) BY MR. GOSS: Q I'm going to hand you what has been marked as your Exhibit 50. This is a document I believe you touched on a bit last week as well. It is another Global Harmonization Task Force document titled Labeling for Medical Devices, dated June 3rd, 2005. What is this document? A As I mentioned, the GHTF published a number of different guidance documents that were arrived at through a number of different steps of coordination amongst industry representatives, manufacturers that means, representatives of manufacturers, and regulators from the various countries that I mentioned. And this is one of the guidance documents that was published by GHTF in final form as one of the guidances that is important to the global model for development and marketing of medical devices. And the particular one is called Labeling for Medical Devices. Q Is this a written standard in the industry	2 3 4 5 6 7 8 9 10 f 11 12 13 14 15 16 17 18 19 is 20 21 22	A All right. Q First of all, did you undertake an investigation to reach an opinion as to whether or not the those sections were adequate? A Yes, I did. Q Okay. We are going to get to the facts supporting your opinions here shortly, but did you reach a conclusion as to whether the Adverse Reaction section in the label was adequate? A Yes, I did. Q And what's that conclusion? A It was not adequate. Q And likewise, with respect to the contraindications and I'm sorry, the Warnings and Precautions section, did you reach a conclusion as to whether or not that section was adequate? A Yes, I did. Q And what was that opinion? A That section also is not adequate. Q Okay. So in your investigation to determine whether or not the Adverse Reaction section, for example, was adequate, what did you do?

8 (Pages 523 to 526)

	Page 527		Page 529
1	some of which we discussed or we just put into evidence	1	associated with the use of the device should be
2	here.	2	included in the product label.
3	I start with that framework, and then I looked	3	(The document referenced below was
4	at company documents with regard to what they knew ar	d 4	marked Deposition Exhibit 52 for
5	when they knew it. I reviewed deposition testimony	5	identification and is appended hereto.)
6	about what was known. I reviewed the medical and	6	BY MR. GOSS:
7	scientific literature that was relevant. I evaluated	7	Q Okay. Now, let's go to the Warnings and
8	commercial experience in the context of publicly	8	Precautions section of the blue book. I'm going to ask
9	available information that's on a web in a database	9	you the same set of questions.
10	called MAUDE, Manufacturer and User Facility Device	10	I'm going to hand you what's been marked as
11	Experience database, referred, again, to as MAUDE,	11	Deposition Exhibit 52. The Warnings and Precaution
12	M-A-U-D-E, for short, which includes serious adverse	12	section, I believe, is the page before that Adverse
13	reactions and malfunctions and that can result in	13	Reaction section in the blue book.
14	serious adverse reactions or be life-threatening that	14	A The warning section is on page 10 in this
15	are reported to the FDA.	15	copy.
16	This information is available, again,	16	Q Okay. And I'm going to hand you what's been
17	publicly, so a manufacturer like Ethicon can look at	17	marked as Deposition Exhibit 52, and I'm going to asl
18	competitor product adverse events that have occurred as	18	you whether or not that accurately sets forth the
19	well as their own reports and their complaint database.	19	warnings and precautions section set forth in the blue
20	Q Let me ask you a little bit about that. Is	20	book.
21	one of the things you need to know is whether Ethicon	21	A Yes.
22	knew or should have known about a risk?	22	Q What does that slide titled "Warnings and
23	A Yes.	23	Precautions" state?
24	Q Okay. And let me back up a little bit, and	24	A Shall I read it?
25	let's go to the blue book which is marked as Exhibit	25	Q Yes.
	Page 528		Page 530
1	A Two.	1	A "Describe serious adverse reactions
2	Q Exhibit 2. Does the blue book provide for	2	and potential safety hazards, the
3	us what should be in the Adverse Reaction section?	3	limitations in use imposed by them, and
4	A Yes, it does.	4	the steps that should be taken if they
5	Q Okay. What page of the blue book provides	5	occur."
6	that?	6	Secondly: "Include an appropriate
7	A On this copy it is page 12, section 8.	7	warning if there is reasonable evidence
8	Q And what is that entitled?	8	of an association of a serious hazard
9	A Adverse Reactions.	9	with the use of the device. A causal
10	(The document referenced below was	10	relationship need not have been proved."
11	marked Deposition Exhibit 51 for	11	And thirdly: "Include information
12	identification and is appended hereto.)	12	regarding any special care to be
13	BY MR. GOSS:	13	exercised by the practitioner and/or
14	Q Okay. I'm going to hand you what I want	14	patient for the safe and effective use
15	you to keep that in front of you. I'm going to hand to	15	of the device."
16	you a slide that's been marked as Deposition Exhibit 5	1 16	Q Okay. And, again, this is from the blue book;
	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1 -	
17	entitled Adverse Reactions Standard. I'm going to ask	17	is that right?
18	you whether or not have you seen this slide before?	18	A Yes.
18 19	you whether or not have you seen this slide before? A Yes.	18 19	A Yes. Q By the way, would slides 51 and
18 19 20	you whether or not have you seen this slide before? A Yes. Q Okay. Is that standard set forth in the slide	18 19 20	A Yes. Q By the way, would slides 51 and A 52.
18 19 20 21	you whether or not have you seen this slide before? A Yes. Q Okay. Is that standard set forth in the slide marked as Exhibit 51 the standard that's set forth in	18 19 20 21	 A Yes. Q By the way, would slides 51 and A 52. Q 52 assist you if published to the jury,
18 19 20 21 22	you whether or not have you seen this slide before? A Yes. Q Okay. Is that standard set forth in the slide marked as Exhibit 51 the standard that's set forth in the blue book?	18 19 20 21 22	A Yes. Q By the way, would slides 51 and A 52. Q 52 assist you if published to the jury, would they assist you in setting forth your testimony?
18 19 20 21 22 23	you whether or not have you seen this slide before? A Yes. Q Okay. Is that standard set forth in the slide marked as Exhibit 51 the standard that's set forth in the blue book? A Yes, it is.	18 19 20 21 22 23	A Yes. Q By the way, would slides 51 and A 52. Q 52 assist you if published to the jury, would they assist you in setting forth your testimony? A Yes.
18 19 20 21 22	you whether or not have you seen this slide before? A Yes. Q Okay. Is that standard set forth in the slide marked as Exhibit 51 the standard that's set forth in the blue book?	18 19 20 21 22	A Yes. Q By the way, would slides 51 and A 52. Q 52 assist you if published to the jury, would they assist you in setting forth your testimony?

9 (Pages 527 to 530)

Page 533 Page 531 1 having some trouble with my microphone right now. 1 IFU," and that's where I'm going with this line of 2 (Off-the-record discussion.) 2 3 3 MR. GOSS: Okay. All right. We are back. (The document referenced below was 4 BY MR. GOSS: 4 marked Deposition Exhibit 53 for 5 Q Do you know whether or not -- first of all, 5 identification and is appended hereto.) 6 6 strike that. BY MR. GOSS: 7 7 Did you see anything in your investigation Q I'm going to hand to you -- first of all, did 8 8 you assist in the preparation of the slide that sets that reflected whether or not Ethicon had adopted the 9 blue book definitions you just read as their standard? 9 forth the risks known by Ethicon at the time of the 10 A Yes, I did. 10 TVT-O launch that weren't in the IFU? 11 Q And what did you review in that regard? 11 A Yes. 12 A In particular, the deposition of Susan Lin 12 Q Would that slide assist you in presenting your 13 from the regulatory department at Ethicon. 13 testimony to the jury? 14 14 Q Okay. I'm going to hand you what I've marked A Yes. 15 as Exhibit 53, and this is the -- on the front page 15 Q Okay. I'm going to hand you what's been 16 says it is the August 9th, 2013, Volume III --16 marked as Deposition Exhibit 53. 17 actually, I'm going to remove that exhibit. It was the 17 A Thank you. 18 wrong one. We will get back to the Susan Lin actual 18 Q Is that the slide that you assisted in the 19 19 deposition itself. preparation of? 20 But in summary, what do you recall Susan Lin 20 A Yes. 21 testified to with respect to Ethicon and the blue book? 21 Q Okay. Let's kind of figure out where we are 22 22 A That Ethicon had adopted the G91-1 blue book on this. 23 memo on medical device labeling as its standard to 23 So the left side of the slide says "Known 24 follow. 24 Risks," the middle part of the slide says "Source," and 25 25 the right part of the slide says 2010 TVT dash -- I'm Q And is that what you would expect of a Page 532 Page 534 reasonable, prudent manufacturer? 1 sorry, "2010 TVT-O IFU." 2 A Yes. 2 First of all, what is the middle section, 3 Q Okay. So that's a good thing? 3 4 A That's a good thing. 4 A On this particular slide the source reflects 5 Q All right. Okay. So we have gone through the 5 testimony of senior members of Ethicon's development 6 blue book, we have gone through the global marketing. 6 team for the TVT-O. 7 Has the global -- GFTG? Q And are these items under Source items that 8 8 A GHTF. you relied upon in making a determination as to whether 9 9 a risk was known or should have been known by Ethicon? Q G -- I'm sorry. 10 10 A That's okay. A Yes. And there is one source here that 11 actually is a document in addition to the others being 11 Q GHTF. 12 You have described what needs to be in the 12 testimony. 13 Adverse Reaction section. You -- I believe your 13 Q Okay. So let's just walk through the slide. 14 testimony was that in order to determine whether or not 14 On the first page it says "Dyspareunia." 15 the 2010 Adverse Reaction section and Precautions and 15 What's dyspareunia? 16 Warnings sections were adequate, you needed to know 16 A Painful sex, painful intercourse. 17 what Ethicon knew or should have known? 17 Q And you have on the slide as your source 18 A That's correct. 18 Catherine Beath, Martin Weisberg. Who are those 19 19 Q And did you endeavor to do that? people? 20 20 A Catherine Beath was head of regulatory A Yes, I did. 21 21 Q Okay. All right. I'm going to hand to you -affairs, and Martin Weisberg was medical director. 22 MR. GOSS: And for the folks on the phone, there's 22 Q Okay. What's regulatory affairs? 23 a slide that I forwarded to you that's entitled -- it 23 A Regulatory affairs is the part of the company is about a five-page slide entitled "Risk Known by 24 that deals with -- with standards, regulations, and 24 25 Ethicon at the Time of TVT-O Launch Not in the TVT-O particularly FDA -- in particular FDA matters.

10 (Pages 531 to 534)

Page 535 Page 537 1 Q So just so we are clear, as we walk through 1 stress urinary incontinence. So recurrence of 2 this slide, when you list, for example, Martin 2 incontinence would be a failure of performance of the 3 3 device for its intended use. Weisberg's testimony, it is next to dyspareunia, what 4 is that telling us? 4 Q And should that have been --5 A It is telling us that he -- he acknowledged 5 MR. LEWIS: Objection. 6 6 BY MR. GOSS: that dyspareunia was a known risk. 7 Q At the --7 O Should that have been in the TVT-O IFU in 8 8 MR. LEWIS: Objection. Form. 2010? 9 BY MR. GOSS: 9 A Yes. 10 O At the time of the launch? 10 Q And would a reasonable and prudent 11 A Yes. 11 manufacturer applying the standards in the industry 12 Q And when you say "acknowledge," is that what 12 have put it in the Adverse Reaction section of the IFU? 13 these deposition cites relate to? 13 A Yes. 14 14 A Yes. This is deposition testimony that Q Okay. And what do you rely upon in support of 15 confirms that the company knew about these risks. 15 their knowledge? 16 Q Okay. So then it says for dyspareunia, for 16 A In this case, as cited here, Ms. Beath's 17 example, 2010 TVT-O IFU, "No." 17 deposition testimony. 18 What does that mean? 18 Q Okay. Let's just continue going down this. "Inflammation/chronic foreign-body reaction." 19 19 A That means that there was no listing of an 20 adverse reaction or a warning with regard to 20 First of all, what is that? 21 dyspareunia in the 2010 IFU that was in use at the time 21 A We were discussing earlier the chronic 22 of Ms. Ramirez's surgery. 22 foreign-body reaction. The inflammation that results 23 Q Would a reasonable and prudent manufacturer 23 from that. Because polypropylene is plastic, it is a 24 applying the standards in the industry that we have 24 foreign body. When it is implanted in the body, the 25 talked about had included dyspareunia in the Adverse 25 body mounts a foreign-body reaction to it, and it is --Page 536 Page 538 1 in contrast to what the TVT-O IFU actually said, that 1 Reactions section? 2 A Definitely. 2 foreign-body reaction and inflammation can be chronic 3 Q The next one is, "Vaginal scarring leading to 3 and that can be associated with risk. 4 significant decrease in quality of life," and the 4 And so that was confirmed by the testimony of 5 5 source is Beath deposition testimony. Dr. Hinoul, Piet Hinoul, also a medical director, and 6 Again, explain to us what that means. 6 Dr. Weisberg, who we talked about also, a medical 7 A That, again, means that this was -- there was 7 director. 8 testimony that this was a known adverse event, a known 8 MR. LEWIS: Objection. Nonresponsive. 9 9 risk of use of the TVT-O device, and it was not BY MR. GOSS: 10 10 included as a risk in the 2010 IFU, which was the IFU Q Who confirmed that? A Dr. Hinoul, Dr. Piet Hinoul, and Dr. Weisberg. 11 in use at the time of Ms. Ramirez's surgery. 11 12 Q And for each of these things that are in 12 Who is Dr. Piet Hinoul? 13 yellow, each of these risks in yellow, what does that 13 A Worldwide medical director at one point, if I 14 denote? 14 recall correctly. 15 A This denotes that these are -- these are 15 O What's a medical director? 16 complications that Ms. Ramirez has been reported to 16 A In key -- in -- a physician. 17 have experienced. 17 Q Okay. 18 Q Okay. And let's just go down this. So 18 A He is a doctor, a physician, at Ethicon with a recurrence of incontinence. First of all, what is 19 19 key role in product development providing medical input 20 20 that? into product development, reviewing -- reviewing safet 21 A Incontinence, Ms. Ramirez had surgery for 21 risk information, evaluating from a medical standpoint 22 22 stress urinary incontinence, which is an involuntary the safety and efficacy of products. 23 leakage of urine with intra-abdominal pressure such as 23 There are a number of different roles that 24 is caused by coughing or exercise, jumping, for 24 people in -- that physicians in medical affairs will 25 example, and the TVT-O device is intended to treat 25

	Page 539		Page 541
1	Q The slides that we marked as Exhibits 51 and	1	section of the 2010 IFU?
2	52 setting forth the adverse reaction standard and	2	A Yes.
3	warnings and precautions standard, and I believe you	3	Q And, again, everything in yellow is something
4	testified that those came from the blue book, would	4	that Jennifer Ramirez has alleged that she has
5	these be in compliance with the Global Harmonization		experienced; is that correct?
6	Task Force requirements as well?	6	A That is correct.
7	A Yes.	7	Q The next known risk, "nerve damage that can
8	Q Okay.	8	cause lifelong pain."
9	A Thank you.	9	First of all, what's that?
10	Q Okay. Let's go to let's go to the next	10	A It could be some type of damage to the nerve.
11	one. First of all, the inflammation and chronic	11	It could be irritation of the nerve. It could be
12	foreign-body reaction, should that have been in the	12	during implantation of the device, an impact on the
13	2010 IFU, that risk?	13	
14	·	14	There are different turnes of demage to the
	A What it says in the 2010 IFU is that	15	There are different types of damage to the
15	inflammation may result and there may be a transit	16	nerve that could occur, but that nerve damage could be
16	may result let me see if I can find the specific		long-term and result in pain and other types of
17	language.	17	complications.
18	That "transitory local irritation at the wound	18	Q Is there anything in the IFU relating to
19	site and a transitory foreign-body reaction may occur,	19	long-term nerve damage that could cause lifelong pain
20	and this response could result in inflammation." And	20	A No. There is not.
21	there it says transitory, meaning brief. It does not	21	Q Would a reasonable and prudent manufacturer
22	mean chronic; so that is misleading.	22	applying the standards in the industry have included
23	Q Okay. Let's go to should should the	23	that in the IFU?
24	belief strike that.	24	A Definitely.
25	The risk of chronic foreign-body reaction,	25	Q Chronic pain is the next one.
	Page 540		Page 542
1	Page 540 should that have been disclosed in the IFU?	1	Page 542 What does that mean?
1 2		1 2	
	should that have been disclosed in the IFU?		What does that mean?
2	should that have been disclosed in the IFU? A Yes. Definitely.	2	What does that mean? A Chronic pain means long-term pain that just
2	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent	2	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time.
2 3 4	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry	2 3 4	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg?
2 3 4 5	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so?	2 3 4 5	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition
2 3 4 5 6	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes.	2 3 4 5 6	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician.
2 3 4 5 6 7	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No.	2 3 4 5 6 7	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU?
2 3 4 5 6 7 8	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU?	2 3 4 5 6 7 8	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction
2 3 4 5 6 7 8	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a	2 3 4 5 6 7 8 9	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent
2 3 4 5 6 7 8 9	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of	2 3 4 5 6 7 8 9	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry
2 3 4 5 6 7 8 9 10	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract.	2 3 4 5 6 7 8 9 10	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU?
2 3 4 5 6 7 8 9 10 11 12	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that	2 3 4 5 6 7 8 9 10 11 12 13	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a
2 3 4 5 6 7 8 9 10 11 12 13 14	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract	2 3 4 5 6 7 8 9 10 11 12 13	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a risk, yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract infections prior to launch?	2 3 4 5 6 7 8 9 10 11 12 13 t 14	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a risk, yes. Q The next one, "Chronic groin, thigh, leg,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract infections prior to launch? A Dr	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a risk, yes. Q The next one, "Chronic groin, thigh, leg, pelvic and/or abdominal pain."
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract infections prior to launch? A Dr MR. LEWIS: Objection. Form.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a risk, yes. Q The next one, "Chronic groin, thigh, leg, pelvic and/or abdominal pain." Would your testimony for that be the same as
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract infections prior to launch? A Dr MR. LEWIS: Objection. Form. THE WITNESS: Dr. Piet Hinoul.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a risk, yes. Q The next one, "Chronic groin, thigh, leg, pelvic and/or abdominal pain." Would your testimony for that be the same as your testimony for chronic pain?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract infections prior to launch? A Dr MR. LEWIS: Objection. Form. THE WITNESS: Dr. Piet Hinoul. BY MR. GOSS:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a risk, yes. Q The next one, "Chronic groin, thigh, leg, pelvic and/or abdominal pain." Would your testimony for that be the same as your testimony for chronic pain? A Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract infections prior to launch? A Dr MR. LEWIS: Objection. Form. THE WITNESS: Dr. Piet Hinoul. BY MR. GOSS: Q Okay. And is there anything regarding the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a risk, yes. Q The next one, "Chronic groin, thigh, leg, pelvic and/or abdominal pain." Would your testimony for that be the same as your testimony for chronic pain? A Yes. Q And the next one, "One or more revisions may
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract infections prior to launch? A Dr MR. LEWIS: Objection. Form. THE WITNESS: Dr. Piet Hinoul. BY MR. GOSS: Q Okay. And is there anything regarding the risk of urinary tract infection in the 2010 IFU?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a risk, yes. Q The next one, "Chronic groin, thigh, leg, pelvic and/or abdominal pain." Would your testimony for that be the same as your testimony for chronic pain? A Yes. Q And the next one, "One or more revisions may be necessary to treat adverse reactions."
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract infections prior to launch? A Dr MR. LEWIS: Objection. Form. THE WITNESS: Dr. Piet Hinoul. BY MR. GOSS: Q Okay. And is there anything regarding the risk of urinary tract infection in the 2010 IFU? A No, there is not.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a risk, yes. Q The next one, "Chronic groin, thigh, leg, pelvic and/or abdominal pain." Would your testimony for that be the same as your testimony for chronic pain? A Yes. Q And the next one, "One or more revisions may be necessary to treat adverse reactions." Would your testimony for that be the same as
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract infections prior to launch? A Dr MR. LEWIS: Objection. Form. THE WITNESS: Dr. Piet Hinoul. BY MR. GOSS: Q Okay. And is there anything regarding the risk of urinary tract infection in the 2010 IFU? A No, there is not. Q Would a reasonable and prudent manufacturer	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a risk, yes. Q The next one, "Chronic groin, thigh, leg, pelvic and/or abdominal pain." Would your testimony for that be the same as your testimony for chronic pain? A Yes. Q And the next one, "One or more revisions may be necessary to treat adverse reactions." Would your testimony for that be the same as your testimony for chronic pain?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	should that have been disclosed in the IFU? A Yes. Definitely. Q And would a reasonable and prudent manufacturer applying the standards in the industry have done so? A Yes. Q Was it in the IFU? A No. Q Okay. Urinary tract infection, what's a urinary tract infection? A It is infection of could be infection of the bladder, the urinary tract. Q Who is your source for your opinion that Ethicon knew or should have known about urinary tract infections prior to launch? A Dr MR. LEWIS: Objection. Form. THE WITNESS: Dr. Piet Hinoul. BY MR. GOSS: Q Okay. And is there anything regarding the risk of urinary tract infection in the 2010 IFU? A No, there is not.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	What does that mean? A Chronic pain means long-term pain that just doesn't go away after a short period of time. Q And the source is the Weisberg deposition testimony. Again, who is Weisberg? A Medical director at Ethicon, a physician. Q Is chronic pain listed as an adverse reaction in the 2010 IFU? A No, it is not. Q And would a reasonable and prudent manufacturer applying the standards in the industry have included chronic pain in the 2010 IFU? A That definitely should have been included as a risk, yes. Q The next one, "Chronic groin, thigh, leg, pelvic and/or abdominal pain." Would your testimony for that be the same as your testimony for chronic pain? A Yes. Q And the next one, "One or more revisions may be necessary to treat adverse reactions." Would your testimony for that be the same as

12 (Pages 539 to 542)

with the implantation of the TVT-O device may not be cured, may not go away. Q And is that something was that included in the 2010 IFU? A No. Q Is that something that a reasonable and prudent manufacturer applying the standards in the the regard to row and the powerPoint that we discussed last week during your deposition? A Yes. And there are other documents with regard to roping and fraying and particle loss as well Q And is the PowerPoint that discussing is the PowerPoint that is reflected there the same		Page 543		Page 545
de with the implantation of the TVT-O device may not be cured, may not go away. 6 Q And is that something was that included in the 2010 IFU? 8 A No. 9 Q Is that something that a reasonable and prudent manufacturer applying the standards in the industry would have included in the 2010 IFU? 12 A Yes, it should have been. 13 Q Moving on, "Additional surgeries to treat and adverse reactions may not resolve those adverse reactions." 15 That's similar to the one we just talked about? 16 A That's correct. 17 Q Would your testimony be the same? 18 A That's correct. 19 Q Would your testimony be the same? 20 A Yes. 21 Q "De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of its is- all of the urine. 24 its all of the urine. 25 Q And was that a risk that your investigation Page 544 1 uncovered that Ethicon knew about? A Yes. 1 Q And would your testimony be the same for de novo urige incontinence? 5 A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 544 1 uncovered that Ethicon knew about? A Yes. Page 5	1	what does that mean?	1	A Yes.
de adverse reactions that have been reported can occul with the implantation of the TVT-O device may not be cured, may not go away. 6 Q And is that something was that included in the 2010 IFU? 8 A No. 9 Q Is that something that a reasonable and prudent manufacturer applying the standards in the 11 industry would have included in the 2010 IFU? 12 A Yes, it should have been. 13 Q Moving on, "Additional surgeries to treat 14 adverse reactions may not resolve those adverse 15 reactions." 16 That's similar to the one we just talked 16 That's similar to the one we just talked 17 about? 18 A That's correct. 19 Q Would your testimony be the same? 21 Q De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of 24 its all of the urine. 25 Q And was that at risk that your investigation Page 544 1 uncovered that Ethicon knew about? 2 A Yes. 3 Q And would your testimony be the same for 4 de novo urge incontinence? 4 A Yes. 4 Yes. 4 Cokay. All right. The last page of this 4 the last page of this slide has some other known risks and I see they are not in yellow. Does that mean the respect to venous thrombosis, abscess formation, hematuria, and mesh erosion leading to significant decrease in quality of life, is your testimony about those risks the same as what we just discussed with to others? A Yes. 9 A Here, as noted, Dr. Weisberg's deposition 10 testimony. 11 Q And was that a risk that your investigation 12 Than the correct of the IFU. 13 A No, they were not. 14 Q And what's your source for all three of those! 15 If m not sure this one is much better. 16 MR. GOSS: Do the folks on the phone have what about to give? 17 Im marking them as a combined actually, 17 Im going to mark the Warnings and Precautions sections as a 54, the Adverse Reactions and Actions sections as a 54, the Adverse Reactions and Actions sections as a 54, the Adverse Reactions and Actions sections as a 54, the Adverse Reactions and Actions sections as a 54, the Adverse Reactions and Actions sections as	2	A That means that even with treatment, some of	2	Q Okay. You cite as your source an email from
with the implantation of the TVT-O device may not be curred, may not go away. Q And is that something was that included in the 2010 IFU? B A No. Q Is that something that a reasonable and prudent manufacturer applying the standards in the industry would have included in the 2010 IFU? A Yes, it should have been. A Yes, it should have been. That's similar to the one we just talked about? A That's similar to the one we just talked about? A Yes. Would your testimony be the same? What is that? A Yes. A Page 544 uncovered that Ethicon knew about? A Yes. BABaically the bladder does not empty all of the urine. A Yes. BABaically the bladder does not empty all of the urine. BAB What is that your investigation A Yes. BAB What is the Yewere not. A Wes. BA Definitely. A A Pefinitely. A A Pefinitely. A A Pefinitely	3	the adverse reactions that have been reported can occur	3	Gene Kammerer dated August 26, 2006, regarding LCN
5 cured, may not go away. 6 Q And is that something — was that included in 7 the 2010 IFU? 7 A Yes. A No. 8 A No. 9 Q Is that something that a reasonable and 10 prudent manufacturer applying the standards in the industry would have included in the 2010 IFU? 12 A Yes, it should have been. 13 Q Moving on, "Additional surgeries to treat adverse reactions." 14 adverse reactions may not resolve those adverse reactions." 15 That's similar to the one we just talked 17 about? 18 A That's correct. 19 Q Would your testimony be the same? 20 A Yes. 21 Q "De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of 24 its — all of the urine. 25 Q And was that a risk that your investigation 26 A Yes. 3 Q And would your testimony be the same for 4 de novo urge incontinence? 4 A Yes. 3 Q And would your testimony be the same for 4 de novo urge incontinence? 4 A Yes. 3 Q And what's your source for all three of those? 4 A Yes. 3 Q And what's your source for all three of those? 4 A Yes. 4 Q And there are other documents with regard to roping and fraying and particle loss as well 7 when the PowerPoint that is reflected there the same 10 powerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected there the same 12 he PowerPoint that is reflected and the 12 he PowerPoint that is reflected and the same as what we some other howerPowerPoint that is reflected and the same and 13 the PowerPoint that is reflected and the same and 13 the powerPoint	4	with the implantation of the TVT-O device may not be	4	versus MCM, and a PowerPoint.
6 Q And is that something was that included in the 2010 IFU? 8 A No. 9 Q Is that something that a reasonable and 10 prudent manufacturer applying the standards in the 11 industry would have included in the 2010 IFU? 12 A Yes, it should have been. 13 Q Moving on, "Additional surgeries to treat 1 adverse reactions may not resolve those adverse 1 tabout? 15 That's similar to the one we just talked 2 about? 16 A That's correct. 17 Q Would your testimony be the same? 18 A That's correct. 19 Q Would your testimony be the same? 20 A Yes. 21 Q 'De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of 24 its all of the urine. 24 Uncovered that Ethicon knew about? 25 Q And was that a risk that your investigation 26 A Yes. 27 A Yes. 28 Q And would your testimony be the same for 4 de novo urge incontinence? 29 A Yes. 20 Q Okay. But is your testimony the same for 4 de novo urge incontinence? 20 A Yes. 21 uncovered that Ethicon knew about? 22 A Yes. 23 A Yes. 24 Q Okay. But is your testimony the same with respect to venous thrombosis, abscess formation, hematuria, and mesh crosion leading to significant decrease in quality of life, is your testimony about those risks the same as what we just discussed with to others? 25 A Yes. 26 Q And would your testimony be the same for 4 de novo urge incontinence? 27 A Yes. 28 Q And would your testimony be the same for 4 de novo urge incontinence? 29 A Here, as noted, Dr. Weisberg's deposition testimony. 21 Q And were those three things addressed in the 2010 TVT-O IFU? 22 A Yes what's they were not. 23 A Yes. 24 Q Okay. But is your testimony the same with respect to venous thrombosis, abscess formation, hematuria, and mesh crosion leading to significant decrease in quality of life, is your testimony those risks the same as what we just discussed with to others? 29 A Yes. 30 Q And would your testimony be the same for 4 de novo urge incontinence? 4 DQ Are those three things addressed in the 2010 TVT-O IFU? 4 Q Are those three things something	5		5	Is that the PowerPoint that we discussed last
7 the 2010 IFU? 8 A No. 9 Q Is that something that a reasonable and 10 prudent manufacturer applying the standards in the 11 industry would have included in the 2010 IFU? 12 A Yes, it should have been. 13 Q Moving on, "Additional surgeries to treat 14 adverse reactions may not resolve those adverse 15 reactions." 16 That's similar to the one we just talked 17 about? 18 A That's correct. 19 Q Would your testimony be the same? 20 A Yes. 21 Q Deay. But is your testimony the same reactions what a risk that your investigation 22 A Yes. 3 Q And was that a risk that your investigation 24 its - all of the urine. 25 Q And was that a risk that your investigation 26 A Yes. 3 Q And would your testimony be the same for 4 de novo urge incontinence? 4 A Yes. 3 Q And would your testimony be the same for 4 de novo urge incontinence? 5 A Yes. 6 Q And word for de novo urinary frequency? 7 A Yes. 8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition 10 testimony. 11 Q And were those three things addressed in the 12 2010 TVT-0 IFU? 13 A No, they were not. 14 Q Are those three things something that a 15 reasonable and draying and fraying and particle loss as well 9 Q And is the PowerPoint that is reflected there the same 10 PowerPoint that's beem marked as Extibits 31 and 32 4 A Yes. 11 PowerPoint that's beem marked as Extibits 31 and 32 4 the last page of this sile has some other known risks 16 the say of this sile has some other known risks 16 at last page of this sile has some other known risks 17 about? 18 A That's correct. 19 Q Wokay. All right. The last page of this 19 the last page of this sile has some other known risks 16 the say of the last page of this sile has some other known risks 16 the say of the last page of this sile has some other known risks 17 amil see they are not in yellow. Does that mean that these are not things that you understand Jennifer 18 A That's correct. 19 Q Okay. Il would like to focus a little bit on the statements that are in the IFU. Okay. And let's g	6		6	week during your deposition?
9 Q Is that something that a reasonable and prudent manufacturer applying the standards in the industry would have included in the 2010 IFU? 12 A Yes, it should have been. 13 Q Moving on, "Additional surgeries to treat adverse reactions." 14 adverse reactions may not resolve those adverse reactions." 15 reactions." 16 That's similar to the one we just talked 16 about? 17 about? 18 A That's correct. 19 Q Would your testimony be the same? 20 A Yes. 21 Q "De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of its - all of the urine. 24 its - all of the urine. 25 Q And was that a risk that your investigation 26 A Yes. 27 Q And was that a risk that your investigation 28 A Yes. 29 Q And was that a risk that pour investigation 29 A Yes. 30 Q And would your testimony be the same for de novo urge incontinence? 4 de novo urge incontinence? 5 A Yes. 6 Q And what's your source for all three of those? 6 Q And what's your source for all three of those? 7 A Yes. 8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition testimony. 10 Q Are those three things addressed in the 2010 TVT-O IFU? 11 Q And were those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 21 A Pagin, what's the yellow? 22 A Yes. 31 C Q And what's vour source for all three of those? 23 A Here, as noted, Dr. Weisberg's deposition testimony. 24 A Yes. 25 D And for the nove urinary frequency? 26 A Yes. 27 A Yes. 28 B W MR. GOSS: 28 B W MR. GOSS: 29 C I'm handing you the Warnings and Precaution sections of the IFU. 30 A No, they were not. 31 A No, they were not. 32 A Pagin, what's the yellow? 33 C O C And here things something that a freasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 31 A No, they were not. 32 A Pagin, wh	7		7	
9 Q Is that something that a reasonable and prudent manufacturer applying the standards in the industry would have included in the 2010 IFU? 12 A Yes, it should have been. 13 Q Moving on, "Additional surgeries to treat adverse reactions may not resolve those adverse reactions." 14 adverse reactions may not resolve those adverse reactions." 15 reactions." 16 That's similar to the one we just talked 16 about? 17 about? 18 A That's correct. 19 Q Would your testimony be the same? 20 A Yes. 21 Q "De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of 24 its - all of the urine. 24 D And was that a risk that your investigation 25 Q And was that a risk that your investigation 26 A Yes. 27 Q And would your testimony be the same for 4 de novo urge incontinence? 28 A Yes. 29 Q And what's your source for all three of those? 29 A Here, as noted, Dr. Weisberg's deposition testimony. 20 A Rethose three things addressed in the 2 2010 TVT-O IFU? 21 A New Wester not. 22 A Yes. 23 A Boefnitely. 24 A Yes. 36 Q And word that Ethicon knew about? 4 D And were those three things addressed in the 2 2010 TVT-O IFU? 4 A No, they were not. 4 Q Okay. Let's go to this last one in yellow. 4 A Definitely. 4 A No, they were not. 4 A Poefnitely. 5 A Pein that is reflected there the same that the been marked as Exhibits 31 and 32 A No, they were not. 4 C Okay. All right. The last page of this slide has some other known risks and I see they are not in yellow. 4 C Okay. But is your testimony the same - with these are not things that you understand Jennifer these are not things that you understand Jennifer are not in yellow. 4 C Okay. But is your testimony the same - with these are not things that we just discussed with to others kis the ame some other known risks and I see they are not in yellow. 4 C Okay. But is your testimony the same - with these are not things that you understand Jennifer Remains and Every are not in yellow. 4 C Okay. But is your testimony the same - with these are not things that your in	8	A No.	8	regard to roping and fraying and particle loss as well.
the PowerPoint that is reflected there the same industry would have been. 12	9	Q Is that something that a reasonable and	9	
11 industry would have included in the 2010 IFU? 12 A Yes, it should have been. 13 Q Moving on, "Additional surgeries to treat adverse reactions may not resolve those adverse reactions may not resolve those adverse reactions may not resolve those adverse reactions." 14 adverse reactions may not resolve those adverse reactions may not resolve those adverse reactions." 15 That's similar to the one we just talked about? 16 That's similar to the one we just talked about? 17 about? 18 A That's correct. 19 Q Would your testimony be the same? 20 A Yes. 21 Q "De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of its all of the urine. 25 Q And was that a risk that your investigation 26 A Yes. 27 Page 544 28 A Yes. 29 A Yes. 29 A Mad would your testimony be the same for de novo urge incontinence? 29 A Yes. 20 Q Okay. Il would like to focus a little bit on the statements that are in the IFU. Okay. And let's go to I'm going to sometimes these IFUs are a little small in the writing I'm not sure this one is much better. 20 A Yes. 21 Q And word how what's your source for all three of those? 22 A Yes. 23 A Yes. 24 Uncovered that Ethicon knew about? 25 A Yes. 26 Q And would your testimony be the same for de novo urge incontinence? 27 A Yes. 28 Q And what's your source for all three of those? 28 A Yes. 29 A Here, as noted, Dr. Weisberg's deposition testimony. 20 A No, they were not. 21 Q Are those three things addressed in the 2010 TVT-O IFU? 21 A No, they were not. 22 A Yes. 23 A Ses. 39 Q And wart's your source for all three of those? 40 A Yes. 41 Uncovered that Ethicon knew about? 42 In uncovered that Ethicon knew about? 43 A Yes. 44 In uncovered that Ethicon knew about? 45 A Yes. 46 Q And for de novo urinary frequency? 47 A Yes. 48 Q And what's your source for all three of those? 49 A Here, as noted, Dr. Weisberg's deposition testimony. 40 A Yes were not. 41 Q Are those three things addressed in the 2010 TVT-O IFU? 41 A No, they were not. 42 A Yes. 43 A No, they were not. 44 A	10		10	the PowerPoint that is reflected there the same
12 A Yes, it should have been. 13 Q Moving on, "Additional surgeries to treat 14 adverse reactions may not resolve those adverse 15 reactions." 16 That's similar to the one we just talked 17 about? 18 A That's correct. 19 Q Would your testimony be the same? 19 Q Would your testimony be the same? 20 A Yes. 21 Q "De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of 24 its - all of the urine. 25 Q And was that a risk that your investigation 26 A Yes. 27 Q And would your testimony be the same for 28 de novo urge incontinence? 29 A Yes. 20 Q And would your testimony be the same for 29 de novo urinary requency? 20 A Yes. 21 Q Okay. But is your testimony the same with 22 those risks the same as what we just discussed with to those risks the same as what we just discussed with to the real title bit on the statements that are in the 24 included in the IFU? 25 Q And were those three things addressed in the 26 Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 20 Q Okay. Let's go to this last one in yellow. 21 A Yes. 22 A Yes. 23 A Pas. 24 That's correct. 25 Q Okay. But is your testimony the same with respect to venous thrombosis, abscess formation, hematuria, and mesh crosion leading to significant decrease in quality of life, is your testimony about those risks the same as what we just discussed with to others? 24 A Yes. 25 A Yes. 26 Q And would your testimony be the same for de novo urge incontinence? 3 IFU. Okay. And let's go to - I'm going to sometimes these IFUs are a little bit on the statements that are in the IFU. Okay. And let's go to - I'm going to sometimes these IFUs are a little bit on the statements that are in the IFU. Okay. And let's go to - I'm going to sometimes these IFUs are a little bit on the statements that are in the IFU. Okay. And let's go to - I'm going to sometimes these IFUs are a little bit on the statements that are in the	11		11	PowerPoint that's been marked as Exhibits 31 and 32?
the last page of this slide has some other known risks reactions." That's similar to the one we just talked about? That's similar to the one we just talked about? Ramirez has complained about? A That's correct. Q Would your testimony be the same? A Yes. Page 544 uncovered that Ethicon knew about? A Yes. Q And was that a risk that your investigation Page 544 uncovered that Ethicon knew about? A Yes. Q And would your testimony be the same for de novo urge incontinence? A Yes. Q And for de novo urinary frequency? A Yes. A Here, as noted, Dr. Weisberg's deposition testimony. A No, they were not. A No, they were not. A Definitely. A Definitely. A A Definitely. A Again, what's the yellow? A Again, what's the yellow? Lie A Definitely. A Again, what's the yellow? A That's correct. Q Okay. But is your testimony the same with respect to venous thrombosis, abscess formation, thematuria, and mesh erosion leading to significant decrease in quality of life, is your testimony about trespect to venous thrombosis, abscess formation, thematuria, and mesh erosion leading to significant decrease in quality of life, is your testimony about the respect to venous thrombosis, abscess formation, thematuria, and mesh erosion leading to significant decrease in quality of life, is your testimony about to respect to venous thrombosis, abscess formation, hematuria, and mesh erosion leading to significant decrease in quality of life, is your testimony be the same for towoer itses the reasonable and protes that go to the same as what we just discussed with to others? A Yes. Page 544 Page 54 Q Okay. I would like to focus a little bit on the - a little bit on the statements that are in the HFU. A Yes. MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got started. The marking them as a combined actually, I'm going to mark the Warnings and Precautions sect as 54, the Adverse Reactions and Actions section	12	•	12	A Yes.
the last page of this slide has some other known risks reactions." That's similar to the one we just talked about? That's similar to the one we just talked about? Ramirez has complained about? A That's correct. Q Would your testimony be the same? A Yes. Page 544 uncovered that Ethicon knew about? A Yes. Q And was that a risk that your investigation Page 544 uncovered that Ethicon knew about? A Yes. Q And would your testimony be the same for de novo urge incontinence? A Yes. Q And for de novo urinary frequency? A Yes. A Here, as noted, Dr. Weisberg's deposition testimony. A No, they were not. A No, they were not. A Definitely. A Definitely. A A Definitely. A Again, what's the yellow? A Again, what's the yellow? Lie A Definitely. A Again, what's the yellow? A That's correct. Q Okay. But is your testimony the same with respect to venous thrombosis, abscess formation, thematuria, and mesh erosion leading to significant decrease in quality of life, is your testimony about trespect to venous thrombosis, abscess formation, thematuria, and mesh erosion leading to significant decrease in quality of life, is your testimony about the respect to venous thrombosis, abscess formation, thematuria, and mesh erosion leading to significant decrease in quality of life, is your testimony about to respect to venous thrombosis, abscess formation, hematuria, and mesh erosion leading to significant decrease in quality of life, is your testimony be the same for towoer itses the reasonable and protes that go to the same as what we just discussed with to others? A Yes. Page 544 Page 54 Q Okay. I would like to focus a little bit on the - a little bit on the statements that are in the HFU. A Yes. MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got started. The marking them as a combined actually, I'm going to mark the Warnings and Precautions sect as 54, the Adverse Reactions and Actions section	13	•	13	Q Okay. All right. The last page of this
15 reactions." 16 That's similar to the one we just talked 17 about? 18 A That's correct. 19 Q Would your testimony be the same? 20 A Yes. 21 Q "De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of its - all of the urine. 25 Q And was that a risk that your investigation 26 A Yes. 27 Q And would your testimony be the same for de novo urge incontinence? 28 A Yes. 29 Q And would your testimony be the same for de novo urge incontinence? 30 Q And what's your source for all three of those? 31 Q And what's your source for all three of those? 32 A Yes. 33 Q And what's your source for all three of those? 34 A Yes. 55 Q And what's your source for all three of those? 45 Q And what's your source for all three of those? 46 Q And what's your source for all three of those? 47 A Yes. 48 Q And what's your source for all three of those? 49 A Here, as noted, Dr. Weisberg's deposition testimony. 40 Q Are those three things addressed in the 2010 TVT-O IFU? 41 A No, they were not. 42 Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 41 A Definitely. 42 A Pes. 43 C And what's the yellow? 44 C Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 44 A Definitely. 45 C A Reactions and Actions sections	14		14	
That's similar to the one we just talked about? A That's correct. Q Would your testimony be the same? A Yes. Dage 544 uncovered that Ethicon knew about? A Yes. Q And would your testimony be the same for de novo urgary frequency? A Yes. Q And for de novo urinary frequency? A Yes. Q And what's your source for all three of those? A Here, as noted, Dr. Weisberg's deposition testimony. Q And were those three things addressed in the creasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? A Q Okay. Let's go to this last one in yellow. A gain, what's the yellow? In Manier has complained about? A That's correct. A A That's correct. B A That's correct. A A That's correct. A A That's correct. B A That's correct. A A That's correct. B A That's correct. B A Yes. D O Okay. But is your testimony the same with respect to venous thrombosis, abscess formation, hematuria, and mesh erosion leading to significant these in quality of life, is your testimony be these risks the same as what we just discussed with to others? A Yes. Page 544 Page 544 Page 54 Me a little bit on the statements that are in the ifful en a little bit on the statements that are in the ifful en a little bit on the statements that are in the ifful en a littl	15	•	15	
17 about? 18 A That's correct. 19 Q Would your testimony be the same? 20 A Yes. 21 Q "De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of its all of the urine. 25 Q And was that a risk that your investigation 26 A Yes. 27 Page 544 28 Uncovered that Ethicon knew about? 29 A Yes. 20 Q And would your testimony be the same for de novo urge incontinence? 30 Q And would your testimony be the same for de novo urge incontinence? 40 A Yes. 41 Uncovered that Ethicon knew about? 42 A Yes. 43 Q And would your testimony be the same for de novo urge incontinence? 44 Yes. 45 Q And hand's your source for all three of those? 46 Q And for de novo urinary frequency? 47 A Yes. 48 Q And what's your source for all three of those? 49 A Here, as noted, Dr. Weisberg's deposition testimony. 40 Q Are those three things addressed in the 2010 TVT-O IFU? 41 Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 41 A Definitely. 42 D O Kay. Let's go to this last one in yellow. 43 A That's correct. 44 C Page 54 Trespect to venous thrombosis, abscess formation, hereafied to verspect to venous thrombosis, abscess formation, hereafied to significant decrease in quality of life, is your testimony about those risks the same as what we just discussed with to others? 4 A Yes. Page 54 Page 54 Page 54 R We. Goss: On the folks on the phone have what about to give? MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got started. 19 C Man draft Ethicon knew about? 10 Let a little bit on the statements that are in the stuff we sent you when we got started. 19 C MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got started. 10 Let a little bit on the statements that are in the same in the	16	That's similar to the one we just talked	16	· ·
18 A That's correct. 19 Q Would your testimony be the same? 20 A Yes. 21 Q "De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of its all of the urine. 25 Q And was that a risk that your investigation Page 544 1 uncovered that Ethicon knew about? 2 A Yes. 3 Q And would your testimony be the same for de novo urge incontinence? 4 de novo urge incontinence? 5 A Yes. 6 Q And for de novo urinary frequency? 7 A Yes. 8 Q And what's your source for all three of those? 8 A Here, as noted, Dr. Weisberg's deposition testimony. 10 testimony. 11 Q And were those three things addressed in the 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 18 A Definitely. 20 Q Kay, I would like to focus a little bit on the statements that are in the 1FU. 21 Q Okay. I would like to focus a little bit on the a little bit on the statements that are in the 1FU. 22 decrease in quality of life, is your testimony about tookers? 23 A Yes. 24 others? 25 A Yes. 26 Page 544 1		·		-
20 A Yes. 21 Q "De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of its all of the urine. 24 uncovered that Ethicon knew about? 25 Q And was that a risk that your investigation 26 A Yes. 27 A Yes. 28 Q And would your testimony be the same for de novo urge incontinence? 30 A Here, as noted, Dr. Weisberg's deposition testimony. 31 Q And what's your source for all three of those? 32 A Here, as noted, Dr. Weisberg's deposition testimony. 33 Q And were those three things addressed in the 2010 TVT-O IFU? 34 A No, they were not. 45 Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 34 A Definitely. 35 A Pesh god Nadi's those in yellow. 36 Page 544 Page 54 Page 64 Page 64 Page 64 Page 54 Page 64 Page 64 Page 64 Page 64 Page 64 Page 64 Page	18	A That's correct.	18	-
20 A Yes. 21 Q "De novo urinary retention." 22 What is that? 23 A Basically the bladder does not empty all of its all of the urine. 24 its all of the urine. 25 Q And was that a risk that your investigation Page 544 1 uncovered that Ethicon knew about? 2 A Yes. Page 544 1 uncovered that Ethicon knew about? 2 A Yes. Q And would your testimony be the same for de novo urge incontinence? 4 A Yes. Q And for de novo urinary frequency? 5 A Yes. Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition testimony. 10 Q And were those three things addressed in the 2 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 18 A Definitely. 20 Again, what's the yellow? 20 Tespect to venous thrombosis, abscess formation, hematuria, and mesh erosion leading to significant decrease in quality of life, is your testimony become and these resion leading to significant decrease in quality of life, is your testimony about to ose; in the stake as what we just discussed with to others? those risks the same as what we just discussed with to others? A Yes. Page 544 Page 54 Page 54 Page 54 Page 54 Ryes. Page 54 Page 54 Page 54 MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: Oper the folks on the phone, you shou have these in the stuff we sent you when we got started. I'm marking them as a combined actually, I'm going to mark the Warnings and Precautions sect as 54, the Adverse Reactions and Actions sections as 54, the Adverse Reactions and Action	19	O Would your testimony be the same?	19	O Okay. But is your testimony the same with
21	20		20	
22 What is that? 23 A Basically the bladder does not empty all of 24 its all of the urine. 25 Q And was that a risk that your investigation Page 544 1 uncovered that Ethicon knew about? 2 A Yes. 3 Q And would your testimony be the same for 4 de novo urge incontinence? 4 A Yes. 6 Q And for de novo urinary frequency? 5 A Yes. 8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition 10 testimony. 11 Q And were those three things addressed in the 12 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 18 A Definitely. 29 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 20 decrease in quality of life, is your testimony about those risks the same as what we just discussed with to others? 24 others? 25 A Yes. 20 decrease in quality of life, is your testimony about those risks the same as what we just discussed with to others? 24 others? 25 A Yes. Page 544 1 Uncovered that Ethicon knew about? 2 A Yes. 2 D Okay. I would like to focus a little bit on the a little bit on the statements that are in the IFU. Okay. And let's go to I'm going to sometimes these IFUs are a little small in the writing 1 MR. GOSS: Do the folks on the phone have what about to give? 3 MS. DIAZ: Yes. 3 BY MR. GOSS: 4 MS. DIAZ: Yes. 4 MS. DIAZ: Yes. 5 BY MR. GOSS: 5 BY MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got started. 1 I'm marking them as a combined actually, I'm going to mark the Warnings and Precautions sect as 54, the Adverse Reactions and Actions sections as	21	O "De novo urinary retention."	21	-
A Basically the bladder does not empty all of its all of the urine. Q And was that a risk that your investigation Page 544 1 uncovered that Ethicon knew about? A Yes. Q And would your testimony be the same for de novo urge incontinence? A Yes. Q And for de novo urinary frequency? A Yes. Q And what's your source for all three of those? A Here, as noted, Dr. Weisberg's deposition testimony. Q And were those three things addressed in the 2010 TVT-O IFU? A No, they were not. Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? A Q Okay. I would like to focus a little bit on the statements that are in the IFU? Q Okay. I would like to focus a little bit on the -a little bit on the statements that are in the IFU. Okay. And let's go to I'm going to 4 sometimes these IFUs are a little small in the writing I'm not sure this one is much better. MR. GOSS: Do the folks on the phone have what about to give? MS. DIAZ: Yes. BY MR. GOSS: Q I'm handing you the Warnings and Precaution sections of the IFU and the Adverse Reactions and Actions section of the IFU. MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got started. I'm going to mark the Warnings and Precautions sections as 54, the Adverse Reactions and Actions sections as 54, the Adverse Reactions and Act		-		
tis all of the urine. Q And was that a risk that your investigation Page 544 1 uncovered that Ethicon knew about? A Yes. Q And would your testimony be the same for de novo urge incontinence? A Yes. Q And for de novo urinary frequency? A Yes. Q And what's your source for all three of those? A Here, as noted, Dr. Weisberg's deposition testimony. Q And were those three things addressed in the 2010 TVT-O IFU? A No, they were not. Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? A Definitely. Q Okay. I would like to focus a little bit on the statements that are in the IFU. Q Okay. I would like to focus a little bit on the statements that are in the IFU. A Yes. Q Okay. I would like to focus a little bit on the statements that are in the IFU. Okay. And let's go to I'm going to sometimes these IFUs are a little small in the writing I'm not sure this one is much better. MR. GOSS: Do the folks on the phone have what about to give? MS. DIAZ: Yes. BY MR. GOSS: BY MR. GOSS: Q I'm handing you the Warnings and Precaution sections of the IFU. MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got started. I'm marking them as a combined actually, I'm going to mark the Warnings and Precautions sections as 44, the Adverse Reactions and Actions sections as 54, the Adverse Reactions and Actions sections	23		23	
Page 544 1 uncovered that Ethicon knew about? 2 A Yes. 3 Q And would your testimony be the same for de novo urge incontinence? 4 de novo urge incontinence? 5 A Yes. 6 Q And for de novo urinary frequency? 7 A Yes. 8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition testimony. 11 Q And were those three things addressed in the 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 2 the a little bit on the statements that are in the IFU. 2 the a little bit on the statements that are in the IFU. Okay. I would like to focus a little bit on the statements that are in the IFU. 2 the a little bit on the statements that are in the IFU. Okay. I would like to focus a little bit on the statements that are in the IFU. Okay. I would like to focus a little bit on the statements that are in the IFU. Okay. I would like to focus a little bit on the statements that are in the IFU. Okay. I would like to focus a little bit on the statements that are in the IFU. Okay. I would like to focus a little bit on the statements that are in the IFU. Okay. And let's go to I'm going to I'm going to I'm going to I'm going to the writing about to give? MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: Do the folks on the phone have what about to give? MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got starte	24		24	·
Page 544 1 uncovered that Ethicon knew about? 2 A Yes. 3 Q And would your testimony be the same for de novo urge incontinence? 4 A Yes. 5 A Yes. 6 Q And for de novo urinary frequency? 7 A Yes. 8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition testimony. 11 Q And were those three things addressed in the 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 And would like to focus a little bit on the statements that are in the 12 Dokay. And let's go to I'm going	25		25	A Yes.
1 uncovered that Ethicon knew about? 2 A Yes. 3 Q And would your testimony be the same for 4 de novo urge incontinence? 4 de novo urge incontinence? 5 A Yes. 6 Q And for de novo urinary frequency? 7 A Yes. 8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition 10 testimony. 11 Q And were those three things addressed in the 12 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 10 Q kay. I would like to focus a little bit on 12 the a little bit on the statements that are in the 13 IFU. Okay. And let's go to I'm going to 2 sometimes these IFUs are a little small in the writing 2 the a little bit on the statements that are in the 3 IFU. Okay. And let's go to I'm going to 2 sometimes these IFUs are a little bit on the statements that are in the 3 IFU. Okay. And let's go to I'm going to 3 sometimes these IFUs are a little bit on the statements that are in the 4 sometimes these IFUs are a little small in the writing 6 MR. GOSS: Do the folks on the phone have what a about to give? 8 MS. DIAZ: Yes. 9 BY MR. GOSS: Q I'm handing you the Warnings and Precautions and 11 sections of the IFU and the Adverse Reactions and 12 Actions section of the IFU. 13 MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got started. 15 I'm marking them as a combined actually, I'm going to mark the Warnings and Precautions sect as 54, the Adverse Reactions and Actions sections and 55.				Page 546
2 A Yes. 3 Q And would your testimony be the same for 4 de novo urge incontinence? 5 A Yes. 6 Q And for de novo urinary frequency? 7 A Yes. 8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition 10 testimony. 11 Q And were those three things addressed in the 12 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 20 the a little bit on the statements that are in the 1FU. Okay. And let's go to I'm going to 4 sometimes these IFUs are a little small in the writing 1FU. Okay. And let's go to I'm going to 4 sometimes these IFUs are a little small in the writing 1FU. Okay. And let's go to I'm going to 4 sometimes these IFUs are a little small in the writing 1FU. Okay. And let's go to I'm going to 4 sometimes these IFUs are a little small in the writing 1FU. Okay. And let's go to I'm going to 4 sometimes these IFUs are a little small in the writing 1FU. Okay. And let's go to I'm going to much better. MR. GOSS: Do the folks on the phone have what about to give? 8 MS. DIAZ: Yes. 9 BY MR. GOSS: 10 Q I'm handing you the Warnings and Precaution sections of the IFU. 11 Actions section of the IFU. 12 Actions section of the IFU. 13 MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got started. 15 I'm going to mark the Warnings and Precautions sections as 54, the Adverse Reactions and Actions sections as 54, the Adverse Reactions are 55.	1		1	
3 IFU. Okay. And let's go to I'm going to 4 de novo urge incontinence? 5 A Yes. 6 Q And for de novo urinary frequency? 7 A Yes. 8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition 10 testimony. 11 Q And were those three things addressed in the 12 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 3 IFU. Okay. And let's go to I'm going to 4 sometimes these IFUs are a little small in the writing 5 I'm not sure this one is much better. 6 MR. GOSS: Do the folks on the phone have what about to give? 8 MS. DIAZ: Yes. 9 BY MR. GOSS: 10 Q I'm handing you the Warnings and Precaution 11 sections of the IFU and the Adverse Reactions and 12 Actions section of the IFU. 13 MR. GOSS: For the folks on the phone, you shou 14 have these in the stuff we sent you when we got 15 started. 16 I'm marking them as a combined actually, 17 I'm going to mark the Warnings and Precautions sections as 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 21 Exhibit 55. 22 (The documents referenced above				-
de novo urge incontinence? A Yes. Q And for de novo urinary frequency? A Yes. Q And what's your source for all three of those? A Here, as noted, Dr. Weisberg's deposition Q And were those three things addressed in the large of the la				
5 A Yes. 6 Q And for de novo urinary frequency? 7 A Yes. 8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition 10 testimony. 11 Q And were those three things addressed in the 12 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 I'm not sure this one is much better. 4 MR. GOSS: Do the folks on the phone have what 5 I'm not sure this one is much better. 4 MR. GOSS: Do the folks on the phone have what 7 about to give? 8 MS. DIAZ: Yes. 9 BY MR. GOSS: 10 Q I'm handing you the Warnings and Precaution sections of the IFU and the Adverse Reactions and 11 sections of the IFU and the Adverse Reactions and 12 Actions section of the IFU. 13 MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got 15 started. 16 I'm marking them as a combined actually, 17 I'm going to mark the Warnings and Precautions sect 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 (The documents referenced above)				
6 Q And for de novo urinary frequency? 7 A Yes. 8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition 10 testimony. 11 Q And were those three things addressed in the 12 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 G NR. GOSS: Do the folks on the phone have what a about to give? 8 MS. DIAZ: Yes. 9 BY MR. GOSS: 10 Q I'm handing you the Warnings and Precaution sections of the IFU and the Adverse Reactions and Actions section of the IFU. 13 MR. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got started. 15 I'm marking them as a combined actually, I'm going to mark the Warnings and Precautions sections as 54, the Adverse Reactions and Actions sections as 54, the Adverse Reactions and Actions sections as Exhibit 55. 20 Again, what's the yellow? 20 (The documents referenced above				-
7 A Yes. 8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition 10 testimony. 11 Q And were those three things addressed in the 12 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 20 A Here, as noted, Dr. Weisberg's deposition 20 BY MR. GOSS: 20 (The documents referenced above)				
8 Q And what's your source for all three of those? 9 A Here, as noted, Dr. Weisberg's deposition 10 testimony. 11 Q And were those three things addressed in the 12 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 BY MR. GOSS: 10 Q I'm handing you the Warnings and Precaution 11 sections of the IFU and the Adverse Reactions and 12 Actions section of the IFU. 13 MR. GOSS: For the folks on the phone, you shou 14 have these in the stuff we sent you when we got 15 started. 16 I'm marking them as a combined actually, 17 I'm going to mark the Warnings and Precautions sect 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 20 (The documents referenced above				-
9 A Here, as noted, Dr. Weisberg's deposition 10 testimony. 11 Q And were those three things addressed in the 12 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 BY MR. GOSS: 10 Q I'm handing you the Warnings and Precaution 11 sections of the IFU and the Adverse Reactions and 12 Actions section of the IFU. 13 MR. GOSS: For the folks on the phone, you shou 14 have these in the stuff we sent you when we got 15 started. 16 I'm marking them as a combined actually, 17 I'm going to mark the Warnings and Precautions sect 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 20 (The documents referenced above				_
testimony. Q And were those three things addressed in the 2010 TVT-O IFU? A No, they were not. Q Are those three things something that a 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? A Definitely. Q Okay. Let's go to this last one in yellow. Q I'm handing you the Warnings and Precaution sections of the IFU and the Adverse Reactions and 12 Actions section of the IFU. A Actions section of the IFU. A MR. GOSS: For the folks on the phone, you shou 14 have these in the stuff we sent you when we got 15 started. I'm marking them as a combined actually, 17 I'm going to mark the Warnings and Precautions sections as 54, the Adverse Reactions and Actions sections as 54, the Adverse Reactions and Actions sections as 19 Q Okay. Let's go to this last one in yellow. Again, what's the yellow? I MR. GOSS: For the folks on the phone, you shou 14 have these in the stuff we sent you when we got 15 started. I'm marking them as a combined actually, 17 I'm going to mark the Warnings and Precautions sect 18 as 54, the Adverse Reactions and Actions sections as 19 Chapter 19 Exhibit 55. (The documents referenced above)	9	· ·		
11 Q And were those three things addressed in the 2010 TVT-O IFU? 12 Actions section of the IFU and the Adverse Reactions and 12 Actions section of the IFU. 13 A No, they were not. 14 Q Are those three things something that a 14 have these in the stuff we sent you when we got 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 16 I'm marking them as a combined actually, 17 included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 21 sections of the IFU and the Adverse Reactions and Heading Turnum Tender T				
12 2010 TVT-O IFU? 13 A No, they were not. 14 Q Are those three things something that a 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 21 Actions section of the IFU. 21 MR. GOSS: For the folks on the phone, you shou 22 have these in the stuff we sent you when we got 23 started. 24 have these in the stuff we sent you when we got 25 started. 26 I'm marking them as a combined actually, 27 I'm going to mark the Warnings and Precautions sect 28 as 54, the Adverse Reactions and Actions sections as 29 (The documents referenced above)		•		
A No, they were not. Q Are those three things something that a reasonable and prudent manufacturer, applying the standards of the industry at that time, would have included in the IFU? A Definitely. Q Okay. Let's go to this last one in yellow. A R. GOSS: For the folks on the phone, you shou have these in the stuff we sent you when we got started. I'm marking them as a combined actually, 17 I'm going to mark the Warnings and Precautions sect as 54, the Adverse Reactions and Actions sections as 54, the Adverse Reactions and Actions sections as 19 Exhibit 55. Again, what's the yellow? O NR. GOSS: For the folks on the phone, you shou have have these in the stuff we sent you when we got started. 15 I'm marking them as a combined actually, 17 I'm going to mark the Warnings and Precautions sect as 54, the Adverse Reactions and Actions sections as 19 Exhibit 55. O CThe documents referenced above		-		
14 Q Are those three things something that a 15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 14 have these in the stuff we sent you when we got 15 started. 16 I'm marking them as a combined actually, 17 I'm going to mark the Warnings and Precautions sect 18 as 54, the Adverse Reactions and Actions sections as 19 Exhibit 55. 20 (The documents referenced above				
15 reasonable and prudent manufacturer, applying the 16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 15 started. 16 I'm marking them as a combined actually, 17 I'm going to mark the Warnings and Precautions sections as 18 as 54, the Adverse Reactions and Actions sections as 19 Exhibit 55. 20 (The documents referenced above				
16 standards of the industry at that time, would have 17 included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 16 I'm marking them as a combined actually, 17 I'm going to mark the Warnings and Precautions sections as 18 as 54, the Adverse Reactions and Actions sections as 19 Exhibit 55. 20 (The documents referenced above				-
17 included in the IFU? 18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 17 I'm going to mark the Warnings and Precautions sections as 54, the Adverse Reactions and Actions sections as 19 Exhibit 55. 20 (The documents referenced above)				
18 A Definitely. 19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 18 as 54, the Adverse Reactions and Actions sections as 19 Exhibit 55. 20 (The documents referenced above				-
19 Q Okay. Let's go to this last one in yellow. 20 Again, what's the yellow? 19 Exhibit 55. 20 (The documents referenced above				
20 Again, what's the yellow? 20 (The documents referenced above		•		
22 reported as having experienced or is experiencing. 22 55 for identification and are appended		=		_
23 Q And the last one on this page, "Roping, 23 hereto.)				
24 fraying and particle loss," is that what we talked 24 BY MR. GOSS:				•

13 (Pages 543 to 546)

1	Page 547		Page 549
1	Exhibit 54. Would this slide assist you in your	1	So that is misleading. It leads the reader to
2	testimony before the jury?	2	believe that any pain that is based on implantation of
3	A Yes, thank you.	3	the TVT-O will go away in a couple of days.
4	Q Is it a little easier to read?	4	Q Is that
5	A It is much easier to read.	5	A With regard to leg pain, I should say.
6	Q Okay. And would your testimony be the same	6	MR. LEWIS: Objection. Nonresponsive. Everythin
7	for Exhibit 55?	7	beginning with "leads the reader."
8	A Yes.	8	BY MR. GOSS:
9	Q Okay. So let's talk about let's talk about	9	Q Does that understate the risk?
10	54 first. Again, we have given the definitions of what	10	A Yes.
11	should go in here. Is there in this Exhibit 54	11	Q What are what, if anything, is improper
12	regarding warnings and precautions, is it mostly	12	about understating risk?
13	precautions or is it warnings? What in here would	13	A It is misleading. It is false. It is
14	actually be a warning?	14	misleading. It puts in the mind of the reader a level
15	MR. LEWIS: Objection. Form.	15	of comfort, if you will, that the risk is minor when in
16	MR. GOSS: Let me strike that question.	16	some patients that risk is not minor.
17	BY MR. GOSS:	17	Q Does that affect public safety?
18	Q For instance, "Ensure that the tape is placed	18	A Yes, it does.
19	with no tension under the mid-urethra."	19	Q Anything else in this Warnings and Precautions
20	Is that considered a warning or a precaution?	20	section that you found misleading or understating risk?
21	A Yes.	21	A Let me just read through them quickly, if I
22	Q Okay. What did you view all of these as a	22	might.
23	representation of some risk?	23	No.
24	MR. LEWIS: Objection. Form.	24	Q Just so we are clear about what the exercise
25	THE WITNESS: These are appropriate. They are	25	was that we just went through, is it your opinion that
	Page 548		Page 550
1	appropriate in terms of for what they state except	1	Deposition Exhibit 53, are these risks in the Warnings
2	where they are misleading, if I may say it that way.	2	and Precautions section?
3	BY MR. GOSS:	3	A Some of them should have gone in the Warning
4	Q Okay. Are there any	4	and Precautions section, yes.
5	MR. LEWIS: Objection. Form.	5	Q Okay. Where should the others have gone?
6	BY MR. GOSS:		Q Okay. Where should the others have gone:
		6	A In the Adverse all of them should be in
7	Q Are there any warnings or precautions that	6 7	
7 8		7	A In the Adverse all of them should be in
	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading?	7	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should
8	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to	7 8	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the fraying
8 9	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones?	7 8 9 10 11	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can
8 9 10	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I	7 8 9 10 11	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the fraying
8 9 10 11 12 13	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom.	7 8 9 10 11 12	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay.
8 9 10 11 12 13 14	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom. "Transient leg pain lasting 24 to	7 8 9 10 11 12 13	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay. A And then those that are serious and
8 9 10 11 12 13 14	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom. "Transient leg pain lasting 24 to 48 hours may occur and can usually be	7 8 9 10 11 12 13 14	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay.
8 9 10 11 12 13 14 15	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom. "Transient leg pain lasting 24 to 48 hours may occur and can usually be managed with mild analgesics."	7 8 9 10 11 12 13 14 15	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay. A And then those that are serious and potentially chronic, those also get included in warnings.
8 9 10 11 12 13 14 15 16	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom. "Transient leg pain lasting 24 to 48 hours may occur and can usually be managed with mild analgesics." Q Okay. And why do you find that misleading?	7 8 9 10 11 12 13 14 15 16	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay. A And then those that are serious and potentially chronic, those also get included in warnings. Q Okay. And so what I'm asking you to do now is
8 9 10 11 12 13 14 15 16 17	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom. "Transient leg pain lasting 24 to 48 hours may occur and can usually be managed with mild analgesics." Q Okay. And why do you find that misleading? A Because while that may be true in a number of	7 8 9 10 11 12 13 14 15 16 17	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay. A And then those that are serious and potentially chronic, those also get included in warnings. Q Okay. And so what I'm asking you to do now is step away from just that and let's look at what's
8 9 10 11 12 13 14 15 16 17 18	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom. "Transient leg pain lasting 24 to 48 hours may occur and can usually be managed with mild analgesics." Q Okay. And why do you find that misleading? A Because while that may be true in a number of patients, there is clinical evidence to reports in	7 8 9 10 11 12 13 14 15 16 17 18	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay. A And then those that are serious and potentially chronic, those also get included in warnings. Q Okay. And so what I'm asking you to do now is step away from just that and let's look at what's actually in the IFU.
8 9 10 11 12 13 14 15 16 17	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom. "Transient leg pain lasting 24 to 48 hours may occur and can usually be managed with mild analgesics." Q Okay. And why do you find that misleading? A Because while that may be true in a number of patients, there is clinical evidence to reports in the literature, for example, that, in fact,	7 8 9 10 11 12 13 14 15 16 17 18 19 20	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the fraying and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay. A And then those that are serious and potentially chronic, those also get included in warnings. Q Okay. And so what I'm asking you to do now i step away from just that and let's look at what's actually in the IFU. A Right.
8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom. "Transient leg pain lasting 24 to 48 hours may occur and can usually be managed with mild analgesics." Q Okay. And why do you find that misleading? A Because while that may be true in a number of patients, there is clinical evidence to reports in the literature, for example, that, in fact, documentation and data that Ethicon had that shows that	7 8 9 10 11 12 13 14 15 16 17 18 19 20 t 21	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay. A And then those that are serious and potentially chronic, those also get included in warnings. Q Okay. And so what I'm asking you to do now is step away from just that and let's look at what's actually in the IFU. A Right. Q And I'm asking you to identify for me the
8 9 10 11 12 13 14 15 16 17 18 19 20	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom. "Transient leg pain lasting 24 to 48 hours may occur and can usually be managed with mild analgesics." Q Okay. And why do you find that misleading? A Because while that may be true in a number of patients, there is clinical evidence to reports in the literature, for example, that, in fact, documentation and data that Ethicon had that shows that leg pain does not always resolve in 48 hours and, in	7 8 9 10 11 12 13 14 15 16 17 18 19 20	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay. A And then those that are serious and potentially chronic, those also get included in warnings. Q Okay. And so what I'm asking you to do now is step away from just that and let's look at what's actually in the IFU. A Right. Q And I'm asking you to identify for me the things that were said and whether or not they
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom. "Transient leg pain lasting 24 to 48 hours may occur and can usually be managed with mild analgesics." Q Okay. And why do you find that misleading? A Because while that may be true in a number of patients, there is clinical evidence to reports in the literature, for example, that, in fact, documentation and data that Ethicon had that shows that leg pain does not always resolve in 48 hours and, in fact, sometimes it is persistent and it may require	7 8 9 10 11 12 13 14 15 16 17 18 19 20 t 21	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay. A And then those that are serious and potentially chronic, those also get included in warnings. Q Okay. And so what I'm asking you to do now is step away from just that and let's look at what's actually in the IFU. A Right. Q And I'm asking you to identify for me the things that were said and whether or not they understated risk or were misleading.
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q Are there any warnings or precautions that were actually in the 2010 TVT-O IFU that you found to be misleading? A Yes. Q Which ones? A Just go down the list. The first one that I see is the fifth up from the bottom. "Transient leg pain lasting 24 to 48 hours may occur and can usually be managed with mild analgesics." Q Okay. And why do you find that misleading? A Because while that may be true in a number of patients, there is clinical evidence to reports in the literature, for example, that, in fact, documentation and data that Ethicon had that shows that leg pain does not always resolve in 48 hours and, in	7 8 9 10 11 12 13 14 15 16 17 18 19 20 t 21 22	A In the Adverse all of them should be in all of those that affect patient safety should that are risks to the patient, I should say basically all of them except the fraying and the particle loss should have been listed in Adverse Reactions. And the frayin and particle loss, the adverse reactions that those can cause should go in the Adverse Reactions section. Q Okay. A And then those that are serious and potentially chronic, those also get included in warnings. Q Okay. And so what I'm asking you to do now is step away from just that and let's look at what's actually in the IFU. A Right. Q And I'm asking you to identify for me the things that were said and whether or not they

14 (Pages 547 to 550)

	Page 551		Page 553
1	Q Okay. Let's go the Adverse Reaction section	1	BY MR. GOSS:
2	which is Exhibit 55.	2	Q You can answer it.
3	A Right.	3	A In terms of potentiating existing infection,
4	Q Let's just take them one at a time.	4	that is fine, but what it doesn't say is infection can
5	"Punctures or lacerations of	5	result. So it is not just it understates that
6	vessels, nerves, bladder, or urethra, or	6	infection de novo, a new infection may occur.
7	bowel may occur during needle passage	7	Q The last one there:
8	and may require surgical repair."	8	"Overcorrection, too much tension
9	Is that misleading or does that understate	9	applied to the tape, may cause temporary
10	risk?	10	or permanent lower urinary tract
11	MR. LEWIS: Objection. Form.	11	obstruction."
12	THE WITNESS: I don't see a problem with that one.	12	Does that is that misleading or does it
13	BY MR. GOSS:	13	understate risk?
14	Q Okay.	14	MR. LEWIS: Objection. Form.
15	"Transitory local irritation at the	15	THE WITNESS: No, because here it actually states
16	wound site and transitory foreign-body	16	that the lower urinary tract obstruction can be
17	response may occur. This response could	17	permanent.
18	result in extrusion, erosion, fistula	18	BY MR. GOSS:
19	formation, or inflammation."	19	Q Okay. There was some discussion last week
20	Does that understate the risk?	20	between you and Ethicon's counsel about whether or no
21	A Yes, it does.	21	duration, frequency, and severity is required to be in
22	Q Is that misleading?	22	the IFU.
23	A Yes, it is.	23	
24		24	Do you recall that? A Yes, I do.
25	MR. LEWIS: Objection. Form.	25	·
			Q At times throughout this IFU, did Ethicon
	Page 552		Page 554
1	BY MR. GOSS:	1	endeavor to put in duration, frequency, or severity?
2	Q Why is that?	2	A Yes, it did.
3	A It is misleading because, as we were talking	3	Q And typically was it when they were trying to
4	earlier, the foreign-body response is not transitory.	4	minimize risk or identify the seriousness of risk?
5	It is chronic. And the inflammation that can then	5	A Yes.
6	result is chronic. So this, again, leads the reader to	6	MR. LEWIS: Object to form.
7	believe that it is brief and it will go away, and	7	THE WITNESS: More often when they were trying
8	indeed that's the documentation testimony supports	8	minimize risk.
9	that is not the case.	9	BY MR. GOSS:
10	Q Let's go to the next one.	10	Q Okay.
11	"As with all foreign bodies,	11	A The only time "permanent" is used is in this
12	Prolene mesh may potentiate an existing	12	last one.
13	infection. The plastic sheaths	13	Q Okay. Let's go under the Actions section.
14	initially covering the Prolene mesh are	14	"Animal studies show that
	designed to minimize the risk and	15	implantation of Prolene mesh elicits a
15	-	16	minimal inflammatory reaction"
15 16	contamination."		
	contamination." Is that misleading or an understatement of	17	Again, is minimal a time does that address
16			Again, is minimal a time does that address severity, duration, intensity?
16 17	Is that misleading or an understatement of risk?	17	_
16 17 18	Is that misleading or an understatement of risk? MR. LEWIS: Objection. Form.	17 18	severity, duration, intensity? A Yes, it does.
16 17 18 19	Is that misleading or an understatement of risk? MR. LEWIS: Objection. Form. MR. GOSS: Tell me what that is so I can cure it.	17 18 19	severity, duration, intensity? A Yes, it does. Q Okay. It "elicits a minimal inflammatory
16 17 18 19 20 21	Is that misleading or an understatement of risk? MR. LEWIS: Objection. Form. MR. GOSS: Tell me what that is so I can cure it. MR. LEWIS: Lack of foundation. Really, lack of	17 18 19 20	severity, duration, intensity? A Yes, it does. Q Okay. It "elicits a minimal inflammatory reaction in tissues, which is transient."
16 17 18 19 20 21 22	Is that misleading or an understatement of risk? MR. LEWIS: Objection. Form. MR. GOSS: Tell me what that is so I can cure it. MR. LEWIS: Lack of foundation. Really, lack of foundation.	17 18 19 20 21	severity, duration, intensity? A Yes, it does. Q Okay. It "elicits a minimal inflammatory reaction in tissues, which is transient." Again, is that dealing with severity,
16 17 18 19 20 21	Is that misleading or an understatement of risk? MR. LEWIS: Objection. Form. MR. GOSS: Tell me what that is so I can cure it. MR. LEWIS: Lack of foundation. Really, lack of	17 18 19 20 21 22	severity, duration, intensity? A Yes, it does. Q Okay. It "elicits a minimal inflammatory reaction in tissues, which is transient."

15 (Pages 551 to 554)

	Page 555		Page 557
1	deposition of a thin fibrous layer of	1	(The document referenced below was
2	tissue that can grow through the	2	marked Deposition Exhibit 57 for
3	interstices"	3	identification and is appended hereto.)
4	Is that right?	4	BY MR. GOSS:
5	A Yes.	5	Q I'm going to ask you I'm going to direct
6	Q "of the mesh, thus incorporating	6	you to page 409 for this transcript, in particular
7	mesh into the adjacent tissue."	7	beginning with line 1 of page 409 through line 13 of
8	This is this is what I want you to focus	8	page 409. And I'm going to also hand you Deposition
9	on:	9	Exhibit 57, which is a slide of that deposition
10	"The material is not absorbed, nor	10	testimony.
11	is it subject to degradation or	11	Will this slide assist you in your have you
12	weakening by the action of tissue	12	seen this slide before?
13	enzymes."	13	A Yes, I have.
14	Does that is that misleading or does it	14	Q Will it assist you in giving your testimony to
15	underplay risk?	15	the jury?
16	MR. LEWIS: Objection. Form.	16	A Yes.
17	THE WITNESS: It is both.	17	Q Okay. Would you please read the slide for me
18	BY MR. GOSS:	18	A Yes.
19	Q Okay. Explain.	19	"Question: And that's Ethicon's
20	A It is false and misleading and underplays the	20	position as you as the spokesperson
21	risk because Ethicon has in its own files, as well as	21	for Ethicon, it is Ethicon's position
22	there are publications, showing that polypropylene is	, 22	that degradation, surface degradation,
23	indeed subject to degradation.	23	can occur; correct?
24	Q Did you see in your investigation into	24	The witness states, Dr. Barbolt, "Yes."
25	Ethicon's conduct, did you see any discussions by	25	"Question: And this was known well
	Page 556		Page 558
1	Ethicon internally regarding degradation?	1	in advance of this statement that the
2	A Yes, I did.	2	material is not absorbed nor is it
3	Q Did you read any testimony by Ethicon	3	subject to degradation; correct?
4	scientists regarding degradation?	4	"Answer: Yes. This is from 1992."
5	A Yes.	5	Q And why do you find that important, if at all?
6	Q Do you understand Thomas Barbolt to be a	6	A It is important because what's included
7	scientist at Ethicon?	7	this is stating that from 1992 the company was aware
8	A Yes.	8	that polypropylene is subject to degradation, yet in
9	Q Did you read any testimony of Thomas Barbolt	9	the IFU, again, the primary communication between th
10	A Yes, I did.	10	company and the doctor, which is supposed to give the
11	(The document referenced below was	11	doctor all the information necessary to use the product
12	marked Deposition Exhibit 56 for	12	safely and effectively and to make decisions as to wha
13	identification and is appended hereto.)	13	is the best treatment to use for a particular patient,
14	BY MR. GOSS:	14	that's not what is stated in the IFU.
15	Q I'm going to hand you what's been marked as	15	Q And then picking up with lines 21 through
16	Exhibit 56 to your deposition. And this is a	16	lines 4 on the next page, could you read that, please,
17	deposition transcript dated January 8th, 2014, for	17	from the slide.
18	Thomas A. Barbolt, Ph.D., given in the MDL.	18	A "Question: Okay. And, number two,
19	Is this document, 56, one of the deposition	19	we know from what we have seen in the
20	transcripts that you reviewed in your investigation of	20	internal studies by Ethicon that the
21	Ethicon's conduct?	21	Prolene and the TVT mesh is susceptible
0.0	A Yes, it is.	22	to surface degradation; correct? Yes,
22			
23	Q And is that something that you relied upon in	23	Doctor?
	Q And is that something that you relied upon in whole or in part for giving your opinions?	23 24	Doctor? "Answer: Yes."

16 (Pages 555 to 558)

	Page 559		Page 561
1	A Again, it shows	1	September 11th, 2013.
2	MR. LEWIS: Objection. Form.	2	Is this one of the deposition transcripts that
3	THE WITNESS: that the information in the IFU	3	you reviewed in forming your opinions in this case?
4	was false and misleading.	4	A Yes, it is.
5	BY MR. GOSS:	5	Q And let me refer you to page 355. just a
6	Q Okay.	6	moment.
7	A And that's in violation of the standard of	7	Okay. Let me refer you to page 1139,
8	care.	8	beginning with line 20, and through 1140, page 1140,
9	Q Okay. Thank you. All right.	9	ending with line 16. Okay. I'm sorry, 1139, line 15
10	MR. LEWIS: Objection. Nonresponsive.	10	is where I want you to pick up.
11	BY MR. GOSS:	11	I'm going to ask you whether or not you read
12	Q I want to talk a little bit we have been	12	that if that testimony is any testimony that you
13	through the IFU, I want to talk with you a little bit	13	reviewed and relied upon in forming your opinions in
14	about some the knowledge, if any, that Ethicon had	14	this case.
15	regarding chronic pain and dyspareunia.	15	A Yes.
16	You have spoken a little bit about transitory.	16	(The document referenced below was
17	What does transitory mean?	17	marked Deposition Exhibit 59 for
18	A Brief.	18	identification and is appended hereto.)
19	Q And we have spoken a little bit about chronic.	19	BY MR. GOSS:
20	What does chronic mean?	20	Q And why don't you read the question and answer
21	A Persistent, long-term.	21	to the jury let me do it this way. Let me show you
22	Q Is chronic just the opposite of transitory?	22	what's been marked as Exhibit 59. Is this a slide that
23	A Yes.	23	you have reviewed that would assist you in your
24	Q Okay. Did you review any testimony from	24	testimony to the jury?
25	Ethicon scientists prior to 2010 when Jennifer Ramire		A Yes.
25	•	22	
	Page 560		Page 562
1	was implanted with the TVT-O where those scientists	1	Q Okay. And is that the testimony the
2	discussed whether or not potential adverse reactions	2	testimony that you relied upon in the deposition
3	were transitory?	3	exhibit?
4	A Yes.	4	A Yes.
5	Q And did you review David Robinson's testimony		Q Okay. Why don't you read that for the jury,
6	A Yes.	6	please.
7	Q Who is David Robinson?	7	A "Question: Now, we talked some
8	A He is also a physician and medical director at	8	about the fact that women who have the
9	Ethicon.	9	TVT implanted can suffer from what's
10	Q Did you review Piet Hinoul's testimony?	10	called dyspareunia or, in other words
11	A Yes.	11	painful sex; correct?
12	Q Who is Piet Hinoul?	12	"Answer: Yes.
13	A Another physician, medical director as well,	13	"Question: Did you warn physicians
14	at Ethicon.	14	that patients could have implantation of
15	Q Did you review James Hart's testimony?	15	the TVT mesh and that could cause
16	A Yes.	16	permanent painful sex?
17	Q Do you recall who James Hart was?	17	"Answer: We did warn against organ
18	A He was also a medical director.	18	damage, the word 'intercourse' and
1			1 2 1 32 3
19	(The document referenced below was	19	'pain' did not appear."
19 20		19 20	Pain' did not appear." Q Why is that important, if at all?
	(The document referenced below was		
20	(The document referenced below was marked Deposition Exhibit 58 for	20	Q Why is that important, if at all? A Because one cannot infer from organ damage
20 21	(The document referenced below was marked Deposition Exhibit 58 for identification and is appended hereto.) BY MR. GOSS: Q Okay. Okay. I'm going to first hand you	20 21	Q Why is that important, if at all?A Because one cannot infer from organ damage
20 21 22	(The document referenced below was marked Deposition Exhibit 58 for identification and is appended hereto.) BY MR. GOSS:	20 21 22	Q Why is that important, if at all? A Because one cannot infer from organ damage permanent painful sex. The permanent painful sex, that

17 (Pages 559 to 562)

	Page 563		Page 565
1	A Is this a good time for a quick break?	1	all, let me mark as Exhibit 61 a slide. I believe you
2	Q Right. I think we have been going for almost	2	have seen this slide before, Exhibit 61?
3	an hour and 15 minutes. Why don't we take about a	3	A Yes.
4	ten-minute break. Is that fine?	4	Q Would that assist you in describing would
5	MR. LEWIS: That sounds fine.	5	that assist you in your testimony to the jury?
6	MS. VERBEEK: Sounds good.	6	A Yes.
7	VIDEO OPERATOR SISSON: This will end Disk 1,	7	Q What is that slide?
8	Volume II, in the deposition of Peggy Pence. 11:37, we	8	A It is it is testimony from Dr. Piet Hinoul.
9	are off the record.	9	Q Is it testimony that's before you in the
10	(Recess taken.)	10	transcript?
11	VIDEO OPERATOR SISSON: At 11:52 we are back on t	ne 11	A Yes.
12	record with the beginning of Disk 2, Volume II, in the	12	Q Okay. Would you please read the testimony
13	deposition of Peggy Pence.	13	that you relied upon of Dr. Hinoul.
14	Counsel, after you.	14	A From the slide?
15	MR. GOSS: Thank you.	15	Q Yes.
16	BY MR. GOSS:	16	A The question is:
17	Q Okay. Dr. Pence, we are back on the record.	17	"The foreign-body reaction or the
18	There was some discussion before we went off the record	18	foreign-body response is chronic;
19	about the IFU and Ethicon's knowledge regarding chronic	19	correct?
20	foreign-body reactions and chronic inflammatory	20	"Answer: Yes. It is a chronic
21	responses.	21	it is a chronic foreign-body reaction."
22	Do you recall that line of questioning?	22	Q And why, if at all, do you find that
23	A Yes, I do.	23	important?
24	(The document referenced below was	24	A Again, because as we noted earlier in the IFU.
25	marked Deposition Exhibit 60 for	25	it says that it is transitory, not chronic, and, as we
	Page 564		Page 566
1	identification and is appended hereto.)	1	discussed earlier, chronic foreign-body
2	BY MR. GOSS:	2	response/chronic inflammation can also lead to
3	Q Okay. I'm going to hand you what's been	3	complications that may be chronic.
4	marked as Exhibit 60.	4	Q Okay. In that same deposition transcript I'm
5	Did you review the deposition of Piet Hinoul	5	going to ask you to turn to page 1156, lines 1 through
6	dated January 14th, 2014, that's been marked as	6	9. Are you there?
7	Deposition Exhibit 60 in forming your opinions in thi	s 7	A Yes.
8	case?	8	Q And is that testimony testimony that you
9	A Yes, I did.	9	relied upon in forming your opinions in this case?
10	Q And is that deposition transcript in whole or	10	A Yes, it is.
11	in part something that you relied upon to form your	11	(The document referenced below was
12	opinions?	12	marked Deposition Exhibit 62 for
	A Yes, it is.	13	identification and is appended hereto.)
13			
13 14	Q I'd ask you to turn to page page 11 I'm	14	BY MR. GOSS:
14 15	Q I'd ask you to turn to page page 11 I'm sorry, page 1144. Okay. And refer you to lines 11,	14 15	BY MR. GOSS: Q And I'm going to hand you what's been marked
14 15 16	Q I'd ask you to turn to page page 11 I'm sorry, page 1144. Okay. And refer you to lines 11, 12, and 13.	14 15 16	BY MR. GOSS: Q And I'm going to hand you what's been marked as Deposition Exhibit 62. Is that a slide that
14 15	Q I'd ask you to turn to page page 11 I'm sorry, page 1144. Okay. And refer you to lines 11, 12, and 13. Do you see there?	14 15 16 17	BY MR. GOSS: Q And I'm going to hand you what's been marked as Deposition Exhibit 62. Is that a slide that reflects that deposition testimony?
14 15 16	Q I'd ask you to turn to page page 11 I'm sorry, page 1144. Okay. And refer you to lines 11, 12, and 13. Do you see there? A Yes, I do.	14 15 16 17 18	BY MR. GOSS: Q And I'm going to hand you what's been marked as Deposition Exhibit 62. Is that a slide that reflects that deposition testimony? A Yes, it is.
14 15 16 17 18 19	Q I'd ask you to turn to page page 11 I'm sorry, page 1144. Okay. And refer you to lines 11, 12, and 13. Do you see there? A Yes, I do. Q Does it start out "foreign-body reaction"?	14 15 16 17 18 19	BY MR. GOSS: Q And I'm going to hand you what's been marked as Deposition Exhibit 62. Is that a slide that reflects that deposition testimony?
14 15 16 17 18 19 20	Q I'd ask you to turn to page page 11 I'm sorry, page 1144. Okay. And refer you to lines 11, 12, and 13. Do you see there? A Yes, I do. Q Does it start out "foreign-body reaction"? A Yes.	14 15 16 17 18 19	BY MR. GOSS: Q And I'm going to hand you what's been marked as Deposition Exhibit 62. Is that a slide that reflects that deposition testimony? A Yes, it is. Q Would that assist you in your testimony before the jury?
14 15 16 17 18 19 20 21	Q I'd ask you to turn to page page 11 I'm sorry, page 1144. Okay. And refer you to lines 11, 12, and 13. Do you see there? A Yes, I do. Q Does it start out "foreign-body reaction"? A Yes. (The document referenced below was	14 15 16 17 18 19 20 21	BY MR. GOSS: Q And I'm going to hand you what's been marked as Deposition Exhibit 62. Is that a slide that reflects that deposition testimony? A Yes, it is. Q Would that assist you in your testimony before the jury? A Yes.
14 15 16 17 18 19 20 21 22	Q I'd ask you to turn to page page 11 I'm sorry, page 1144. Okay. And refer you to lines 11, 12, and 13. Do you see there? A Yes, I do. Q Does it start out "foreign-body reaction"? A Yes. (The document referenced below was marked Deposition Exhibit 61 for	14 15 16 17 18 19 20 21	BY MR. GOSS: Q And I'm going to hand you what's been marked as Deposition Exhibit 62. Is that a slide that reflects that deposition testimony? A Yes, it is. Q Would that assist you in your testimony before the jury? A Yes. Q Could you please read for the jury what
14 15 16 17 18 19 20 21 22 23	Q I'd ask you to turn to page page 11 I'm sorry, page 1144. Okay. And refer you to lines 11, 12, and 13. Do you see there? A Yes, I do. Q Does it start out "foreign-body reaction"? A Yes. (The document referenced below was marked Deposition Exhibit 61 for identification and is appended hereto.)	14 15 16 17 18 19 20 21 22 23	BY MR. GOSS: Q And I'm going to hand you what's been marked as Deposition Exhibit 62. Is that a slide that reflects that deposition testimony? A Yes, it is. Q Would that assist you in your testimony before the jury? A Yes. Q Could you please read for the jury what testimony you relied upon in forming your opinions?
14 15 16 17 18 19 20 21 22	Q I'd ask you to turn to page page 11 I'm sorry, page 1144. Okay. And refer you to lines 11, 12, and 13. Do you see there? A Yes, I do. Q Does it start out "foreign-body reaction"? A Yes. (The document referenced below was marked Deposition Exhibit 61 for	14 15 16 17 18 19 20 21	BY MR. GOSS: Q And I'm going to hand you what's been marked as Deposition Exhibit 62. Is that a slide that reflects that deposition testimony? A Yes, it is. Q Would that assist you in your testimony before the jury? A Yes. Q Could you please read for the jury what

18 (Pages 563 to 566)

	Page 567		Page 569
1	"And scientists who are expert in	1	testimony to the jury?
2	this field the most expert people in the	2	A Yes.
3	world	3	Q Okay. Why did you find and, again, read
4	"Answer: Mm-hmm.	4	Exhibit 63.
5	"Question: would agree that	5	A "Question: And the doctor would
6	there is a chronic inflammatory response	6	be expected to believe, pursuant to what
7	to the	7	it states here, that the inflammatory
8	"Answer: Yes.	8	reaction is only transient because
9	"Question: TVT mesh; correct?	9	that's all it says; correct?
10	"Answer: Correct."	10	"Answer: Correct."
11	Q Okay. And why, if at all, did you find that	11	Q And why is that important?
12	important?	12	A Again, because the IFU is misleading. The IFU
13	A Again, it substantiates that the what we	13	doesn't tell the doctor that the there is the a
14	were discussing earlier. It supports that the	14	chronic inflammatory reaction, chronic foreign-body
15	inflammatory reaction is chronic, it is supported by	15	response, and, therefore, it is again, it is
16	scientists who are expert in the field, and Dr. Hinoul	16	misleading to the doctor in terms of having all the
17	testifies that that is the case, and it is the	17	information necessary for safe and effective use of the
18	·	18	•
19	chronic inflammatory response is not what's stated in the IFU.	19	device and for making a decision as to whether or not
	Q And is that that information the	20	this device is the appropriate treatment for the patient's stress urinary incontinence.
20	-		•
21	testimony that the two pieces of testimony that you	21	MR. LEWIS: Objection. Nonresponsive. BY MR. GOSS:
22	just read, did your investigation determine whether or		
23	not that was information that Ethicon had in its	23	Q Okay. This morning, as you will remember, I
24	possession at the time of launch?	24	wanted to start back up where we left off last time,
25	A Yes.	25	but we didn't have the exhibit here.
	Page 568		Page 570
1	Q Okay.	1	Do you recall?
2	MR. LEWIS: Objection. Form.	2	A Yes, I do.
3	(The document referenced below was	3	Q So I'm going to back up a little bit and
4	marked Deposition Exhibit 63 for	4	discuss where we left off last week.
5	identification and is appended hereto.)	5	Do you remember some discussion at the end of
6	BY MR. GOSS:	6	the deposition last week about a particular lot of mesh
7	Q Let me see the transcript again.	7	that had some problems?
8	I'm going to hand you back Dr. Hinoul's	8	A Yes.
9	testimony that you previously stated that you reviewed,	9	Q Okay. And one of the things we did last week
10	and I'm going to ask you to turn to page 1170, lines 1	10	was we marked the surgical record for Jennifer Ramirez
11	through 6, of that testimony. I'm going to ask you to	11	Do you recall that?
12	review that testimony and tell the jury whether that is	12	A I do.
13	something that you relied upon in forming your opinions	13	Q Let me see if I can find this stack. I'm
14	in this case.	14	going to hand you what's been marked as Exhibit 19.
15	A Page 1170; is that correct?	15	And, again, tell the jury what is Exhibit 19?
16	Q That's correct.	16	A This is a one-page document. It is the
17	A Okay.	17	surgery implant record from Baptist Health System with
18	"Question: And the doctor would be	18	the sticker on it from the TVT-O device that was
19	expected to believe, pursuant to what it	19	implanted in Ms. Ramirez.
20	states here, that the inflammatory	20	Q Okay. And then what does it say is the lot
21	reaction is only transient because	21	number for that?
	that's all it says; correct?	22	A The lot number of TVT-O is 3405428.
22	that's an it says, confect:		
22 23	"Answer: Correct."	23	Q And what is the 810081 number?
	-		

19 (Pages 567 to 570)

	Page 571		Page 573
1	Q And, in your investigation into Ethicon files,	1	A What turned out to be the foreign matter, for
2	did you see any documents where Ethicon had received	2	example, in the case of Ms. Ramirez, was particles
3	any complaints about that particular lot number that is	3	lost. We talked earlier about fraying and particle
4	Jennifer Ramirez's lot number?	4	loss from the mechanically cut mesh. It is particles
5	A Yes, I did.	5	lost from that.
6	Q And we touched on this a little bit last week,	6	Q And was it in the open or unopened package?
7	but do you recall the presentation set forth in	7	A Unopened package.
8	Exhibit 42 of last week?	8	Q Okay. Is the package clear?
9	A Yes, I do.	9	A Yes.
10	Q And what is that document?	10	Q Okay. And I gather then what you are saying
11	A This is a PowerPoint presentation entitled	11	is that you can see particle loss through the unopened
12	"Particle and TVT-O Blisters."	12	clear package?
13	Q And what do you understand that document is	13	A Yes.
14	reflecting?	14	Q And how is that were those complaints
15	A It is discussing the particle loss that has	15	resolved?
16	complaints of particle loss that have been reported to	16	A The complaints were reported to Ethicon, and
17	Ethicon, in particular for the mechanically cut TVT-O	17	Ethicon, for example, they the same hospital that
18	device.	18	reported the two complaints for the lot number that was
19	Q Is Jennifer Ramirez's lot number one of the	19	implanted in Ms. Ramirez also reported two other lot
20	lot numbers for which they had complaints?	20	numbers that had the same issue in a complaint which
21	A Yes, it is.	21	then was investigated, and the results of the
22	Q And how do you know that?	22	investigation were recorded in an Issue Report.
23	A Because, as I just read, the lot number that	23	Q Okay. What's an Issue Report?
24	was implanted in her is 3405428, and on this PowerPoin		A An Issue Report is once it is the form at
25	presentation in a listing of complaints that number	25	Ethicon in which they document the complaint and
	Page 572		Page 574
1	is is identified.	1	results of their investigation of a particular
2	Q Okay. And you have talked generally about	2	complaint and whether or not that investigation results
3	there were complaints. How many complaints were there	? 3	in a determination that the complaint should also be
4	A For her particular lot, there were two.	4	reported as a Medical Device Report meaning that it is
5	Q Okay. And what were there other complaints	5	a report of a serious injury or a life-threatening
6	for other lots?	6	injury or a malfunction that, if it were to recur,
7	A Yes.	7	could result in a serious or life-threatening injury.
8	Q And how many were there?	8	MR. GOSS: The folks on the phone, I'm asking my
9	A This designates six different complaints.	9	associate. Have we sent them the Issue Report?
10	Q Okay. And were they different complaints or	10	MS. DIAZ: Yeah, we did.
11	were they making the same allegation?	11	MR. GOSS: So this was in
12	A They were all making the allegation of foreign	12	MS. DIAZ: Uh-huh.
13	matter in the TVT-O blisters.	13	(The document referenced below was
14	Q Okay. What does that mean "foreign matter in	14	marked Deposition Exhibit 64 for
1 1 5			manue Deposition Emilion o . Tor
15	a blister"? Explain to the jury what a blister is.	15	identification and is appended hereto.)
16	a blister"? Explain to the jury what a blister is.A What they are talking about, the blister is	15 16	identification and is appended hereto.) BY MR. GOSS:
	a blister"? Explain to the jury what a blister is. A What they are talking about, the blister is the packaging in which the device the plastic	15 16 17	identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark as Exhibit 4 [sic] a
16	a blister"? Explain to the jury what a blister is. A What they are talking about, the blister is the packaging in which the device the plastic container, if you will, in which the device is	15 16 17 18	identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark as Exhibit 4 [sic] a document entitled Issue Report.
16 17 18 19	a blister"? Explain to the jury what a blister is. A What they are talking about, the blister is the packaging in which the device the plastic container, if you will, in which the device is packaged, and that is opened	15 16 17 18 19	identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark as Exhibit 4 [sic] a document entitled Issue Report. Dr. Pence, can you please explain to the jury
16 17 18 19 20	a blister"? Explain to the jury what a blister is. A What they are talking about, the blister is the packaging in which the device the plastic container, if you will, in which the device is packaged, and that is opened Q Okay.	15 16 17 18 19 20	identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark as Exhibit 4 [sic] a document entitled Issue Report. Dr. Pence, can you please explain to the jury what this is?
16 17 18 19 20 21	a blister"? Explain to the jury what a blister is. A What they are talking about, the blister is the packaging in which the device the plastic container, if you will, in which the device is packaged, and that is opened Q Okay. A to remove the device, and foreign matter is	15 16 17 18 19 20 21	identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark as Exhibit 4 [sic] a document entitled Issue Report. Dr. Pence, can you please explain to the jury what this is? A Yes. This is the Issue Report that is
16 17 18 19 20 21 22	a blister"? Explain to the jury what a blister is. A What they are talking about, the blister is the packaging in which the device the plastic container, if you will, in which the device is packaged, and that is opened Q Okay.	15 16 17 18 19 20 21 22	identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark as Exhibit 4 [sic] a document entitled Issue Report. Dr. Pence, can you please explain to the jury what this is? A Yes. This is the Issue Report that is associated with complaint CC1007, 005, which is the
16 17 18 19 20 21 22 23	a blister"? Explain to the jury what a blister is. A What they are talking about, the blister is the packaging in which the device the plastic container, if you will, in which the device is packaged, and that is opened Q Okay. A to remove the device, and foreign matter is something in the packaging that is not supposed to be there.	15 16 17 18 19 20 21 22 23	identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark as Exhibit 4 [sic] a document entitled Issue Report. Dr. Pence, can you please explain to the jury what this is? A Yes. This is the Issue Report that is associated with complaint CC1007, 005, which is the complaint that Ethicon received for the particular lot
16 17 18 19 20 21 22	a blister"? Explain to the jury what a blister is. A What they are talking about, the blister is the packaging in which the device the plastic container, if you will, in which the device is packaged, and that is opened Q Okay. A to remove the device, and foreign matter is something in the packaging that is not supposed to be	15 16 17 18 19 20 21 22	identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark as Exhibit 4 [sic] a document entitled Issue Report. Dr. Pence, can you please explain to the jury what this is? A Yes. This is the Issue Report that is associated with complaint CC1007, 005, which is the

20 (Pages 571 to 574)

	Page 575		Page 577
1	in forming your opinions in this case?	1	speed things up a little bit here. Let me ask you
2	A Yes.	2	about the test results on page it is page 350 of 723
3	Q Okay. Is there anything in particular in the	3	of this document that has the last three Bates numbers
4	Issue Report that you relied upon?	4	831. It says:
5	A Yes.	5	"Test results. The blister
6	Q What is that?	6	contains some particles. These
7	A There was a confirmation. For example, there	7	particles come from the mesh and are
8	is a question asked in the Issue Report: "Was it	8	inferior to three millimeters in length.
9	determined that a device-related or patient-related	9	These kind of particles are not
10	event actually did occur?" And the answer was "Yes."	10	considered as foreign matter."
11	MR. GOSS: Let the record reflect that is from	11	My question is what's the significance, if
12	Bates page 02656826, question 2.	12	any, of three millimeters?
13	BY MR. GOSS:	13	MR. LEWIS: Objection. Form.
14	Q Why did you find that important?	14	THE WITNESS: That was a determination, a cutoff,
15	A Because it confirms that there was an issue	15	that Ethicon made to decide when particle loss was an
16	with that the complaint was confirmed, if you will.	16	issue. I did look to see if I could identify any
17	Q Is there anything else in this document that	17	evidence as to why three millimeters, why that was a
18	you relied upon in forming your opinions?	18	cutoff and not two millimeters, for example. And I was
19	A Yes. On question 9. The question Bates	19	not able to find any evidence supporting why three
20	number ending in 827, the question is:	20	millimeters was used as a cutoff.
21	"Does the information reasonably suggest that	21	BY MR. GOSS:
22	the device failed to meet its performance specification		Q Did you see any discussion of any scientific
23	or otherwise failed to perform as intended?"	23	or clinical basis for the use of three millimeters as a
24	And the response is, "Yes."	24	cutoff?
25	Q And why, if any strike that.	25	A No, I did not.
	Page 576		Page 578
1		1	
1 2	Why did you find that important, if at all?		Q Would a reasonable and prudent manufacturer
3	A Again, it is confirmation in the investigation of this complaint that the device failed to meet its	2 3	arbitrarily set a cutoff of three millimeters? A No.
4	performance specifications according to those that wer		Q And if that's what if there is no
5	investigating the complaint.	5	scientific basis or clinical basis for saying the
6	Q Anything else in this report that you found	6	cutoff is at three millimeters or whether or not
	important to your opinions?	7	
7 8	A Yes. The next question:	8	particles are clinically significant, would that be a violation of standards in the industry?
9	"Does information or a medical	9	-
10	rationale exist that states no	10	A Absolutely.
	possibility of death or serious injury		Q Okay. Let's move on a little bit. Let's
11	* * *	11	shift gears to the MAUDE database.
12	occurring as a result of any recurrence	12	Tell the jury what the MAUDE database is.
13	of the malfunction?"	13	A The MAUDE database MAUDE stands for
14	And the response is, "No."	14	Manufacturer and User Facility Device Experience
15	Q What does that mean?	15	database. It is the database into which medical device
16	A Basically the reason that this is important is	16	reports are submitted and the information for those
17	because, as I believe we discussed previously last	17	medical device reports is recorded therein. It is
18	week, that Ethicon had not undertaken any investigatio		publicly available and when I'm talking about
19	to determine whether or not lost particles or the	19	medical device reports, those are reports of serious or
20	fraying that results in the lost particles would have a	20	life-threatening injuries to patients or device
21	safety impact on the patient.	21	malfunctions which, if they were to recur, could result
22	Q What page number were you reading from, Bate		in serious or life-threatening injuries to the patient.
23	page?	23	Post it is for postmarketing safety
24	A Bates ending in 827.	24	information, and it is from postmarketing adverse
25	Q Okay. I'm going to ask you about kind of	25	event reporting is a mechanism which is used to

21 (Pages 575 to 578)

	Page 579		Page 581
1	continue to evaluate postmarketing safety and	1	BY MR. GOSS:
2	performance of a medical device. It is a part of risk	2	Q I'm going to hand you Deposition Exhibit 66.
3	assessment and ongoing risk analysis so that any	3	As I understand it 65 65 includes TVT prior to
4	performance or safety issues that occur are evaluated	4	TVT-O; correct?
5	and fed back into the risk analysis on an ongoing basis		A Correct.
6	for a medical device that is in commercial use to	6	Q Okay. I'm going to hand you what's been
7	determine if anything needs to be done to mitigate any		marked as Exhibit 66 and ask you if this is a slide
8	risk. For example, changes in labeling or additional	8	that will assist you in the giving of your testimony to
9		9	the jury.
	testing.	10	A Yes.
10	Q Okay. And so did you undertake to review the		
11	MAUDE database?	11	Q And what is that exhibit?
12	A Yes, I did.	12	A This exhibit is similar to the one that we
13	Q And is that reflected in your report?	13	were just discussing, but this one is specific to
14	A Yes, it is.	14	TVT-O. It is entitled Ethicon Tension-Free Vaginal
15	Q Okay. And I think we marked your report as	15	Tape Obturator MDRs: Most Commonly Reported Adver
16	Exhibit 7 last week, and Exhibit 7 here I'm sorry,	16	Events 2004 to 2011." The reason it starts in 2004 is
17	it is not Exhibit 7. It is I'm going to refer you	17	because that's consistent with the time frame of the
18	to Exhibit 3, which is your report. And you recall	18	marketing of the TVT-O.
19	your report had a number of tables that reflected the	19	Q Okay. All right. Let me walk you through
20	results of your analysis of the MAUDE database?	20	Exhibit 66.
21	A Yes, I do.	21	A Okay.
22	Q Okay. And did you assist in the preparation	22	Q All right. Again, this is the commonly
23	of some slides that reflect those findings and those	23	reported adverse events from 2004 through 2011; right?
24	tables?	24	A Yes.
25	A Yes.	25	Q The the first event, pain, let's just walk
	Page 580		Page 582
1	(The document referenced below was		
	(The document referenced below was	1	across this. What's the 175 number?
2	·	1 2	across this. What's the 175 number? A That's the total number of medical device
	marked Deposition Exhibit 65 for	2	A That's the total number of medical device
3	marked Deposition Exhibit 65 for identification and is appended hereto.)	2	A That's the total number of medical device reports that included a report of pain.
3 4	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS:	2 3 4	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number
3 4 5	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark	2 3 4 5	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011?
3 4 5 6	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you	2 3 4 5 6	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes.
3 4 5 6 7	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in	2 3 4 5 6 7	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for
3 4 5 6 7 8	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables.	2 3 4 5 6 7 8	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right?
3 4 5 6 7 8 9	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does.	2 3 4 5 6 7 8 9	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct.
3 4 5 6 7 8 9	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your	2 3 4 5 6 7 8 9	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events?
3 4 5 6 7 8 9 10	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury?	2 3 4 5 6 7 8 9 10	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes.
3 4 5 6 7 8 9 10 11	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes.	2 3 4 5 6 7 8 9 10 11	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are
3 4 5 6 7 8 9 10 11 12	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65?	2 3 4 5 6 7 8 9 10 11 12	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those?
3 4 5 6 7 8 9 10 11 12 13	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65? A Exhibit 65, on the left-hand side is a	2 3 4 5 6 7 8 9 10 11 12 13	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those? A That number reflects what the actual incidence
3 4 5 6 7 8 9 10 11 12 13 14	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65? A Exhibit 65, on the left-hand side is a tabulation of the	2 3 4 5 6 7 8 9 10 11 12 13 14 15	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those? A That number reflects what the actual incidence could be if based on consideration that we know that
3 4 5 6 7 8 9 10 11 12 13 14 15 16	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65? A Exhibit 65, on the left-hand side is a tabulation of the Q First of all, what is it entitled?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those? A That number reflects what the actual incidence could be if based on consideration that we know that there's underreporting of events
3 4 5 6 7 8 9 10 11 12 13 14 15 16	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65? A Exhibit 65, on the left-hand side is a tabulation of the Q First of all, what is it entitled? A Oh. Sorry. "Ethicon Tension-Free Vaginal	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those? A That number reflects what the actual incidence could be if based on consideration that we know that there's underreporting of events Q How do we know that?
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65? A Exhibit 65, on the left-hand side is a tabulation of the Q First of all, what is it entitled? A Oh. Sorry. "Ethicon Tension-Free Vaginal Tape MDRs," standing for Medical Device Reports, "Mo	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those? A That number reflects what the actual incidence could be if based on consideration that we know that there's underreporting of events Q How do we know that? A to the MAUDE database.
3 4 5 6 7 8 9 10 11 12 13 14 15 16	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65? A Exhibit 65, on the left-hand side is a tabulation of the Q First of all, what is it entitled? A Oh. Sorry. "Ethicon Tension-Free Vaginal Tape MDRs," standing for Medical Device Reports, "Mc Commonly Reported Adverse Events from 1999 to 2010	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those? A That number reflects what the actual incidence could be if based on consideration that we know that there's underreporting of events Q How do we know that? A to the MAUDE database. It is published in the scientific medical
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65? A Exhibit 65, on the left-hand side is a tabulation of the Q First of all, what is it entitled? A Oh. Sorry. "Ethicon Tension-Free Vaginal Tape MDRs," standing for Medical Device Reports, "Mo	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those? A That number reflects what the actual incidence could be if based on consideration that we know that there's underreporting of events Q How do we know that? A to the MAUDE database.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65? A Exhibit 65, on the left-hand side is a tabulation of the Q First of all, what is it entitled? A Oh. Sorry. "Ethicon Tension-Free Vaginal Tape MDRs," standing for Medical Device Reports, "Mc Commonly Reported Adverse Events from 1999 to 2010	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 st 18	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those? A That number reflects what the actual incidence could be if based on consideration that we know that there's underreporting of events Q How do we know that? A to the MAUDE database. It is published in the scientific medical
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65? A Exhibit 65, on the left-hand side is a tabulation of the Q First of all, what is it entitled? A Oh. Sorry. "Ethicon Tension-Free Vaginal Tape MDRs," standing for Medical Device Reports, "Mc Commonly Reported Adverse Events from 1999 to 2010 Q Okay. I'm going to now give me one second.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 st 18 ' 19 20	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those? A That number reflects what the actual incidence could be if based on consideration that we know that there's underreporting of events Q How do we know that? A to the MAUDE database. It is published in the scientific medical literature, and there is a report, for example, from
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65? A Exhibit 65, on the left-hand side is a tabulation of the Q First of all, what is it entitled? A Oh. Sorry. "Ethicon Tension-Free Vaginal Tape MDRs," standing for Medical Device Reports, "McCommonly Reported Adverse Events from 1999 to 2010 Q Okay. I'm going to now give me one second. I'm going to hand you what was that last number?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 st 18 ' 19 20 21	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those? A That number reflects what the actual incidence could be if based on consideration that we know that there's underreporting of events Q How do we know that? A to the MAUDE database. It is published in the scientific medical literature, and there is a report, for example, from FDA that Congress that reflects that Congress
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	marked Deposition Exhibit 65 for identification and is appended hereto.) BY MR. GOSS: Q Okay. I'm going to mark I'm going to mark as Deposition Exhibit 65 a slide. I'm going to ask you if this reflects the information that was set forth in one of your tables. A Yes, it does. Q And will this slide assist you in giving your testimony to the jury? A Yes. Q Okay. What is Exhibit 65? A Exhibit 65, on the left-hand side is a tabulation of the Q First of all, what is it entitled? A Oh. Sorry. "Ethicon Tension-Free Vaginal Tape MDRs," standing for Medical Device Reports, "Mc Commonly Reported Adverse Events from 1999 to 2010 Q Okay. I'm going to now give me one second. I'm going to hand you what was that last number? A 65.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 st 18 ' 19 20 21 22	A That's the total number of medical device reports that included a report of pain. Q And then what is and is that a total number from 2004 through 2011? A Yes. Q Okay. And I see it goes all the way down for erosion, urinary problems, et cetera; right? A That's correct. Q And those are all events? A Yes. Q Okay. What is the numbers in red, what are those? A That number reflects what the actual incidence could be if based on consideration that we know that there's underreporting of events Q How do we know that? A to the MAUDE database. It is published in the scientific medical literature, and there is a report, for example, from FDA that Congress that reflects that Congress estimates that, for medical devices, as few as 1 in 100

22 (Pages 579 to 582)

	Page 583		Page 585
1	A Okay.	1	Q Okay. Let's talk about Exhibit 67. Again, is
2	Q So if there's 175 actual I'm sorry, if	2	this the information that was in one of your tables in
3	there are 175 reported events to the MAUDE database	- 3	your report?
4	A Right.	4	A Yes. In an exhibit to my report, yes.
5	Q based upon the studies and the	5	Q And is the information gathered from the MAUD
6	congressional reports that you have just discussed,	6	database?
7	what would they estimate to be the potential adverse	7	A That's correct.
8	events that are actually out there relating to pain?	8	Q Okay. And so what is this exhibit?
9	A 17,500.	9	A This is a breakdown of the 57 reports of
10	Q Okay. And so for erosion with 159 reports,	10	sexual dysfunction that we identified in the MAUDE
11	what's the potential number of reports based if you	11	database into what those 57 reports the terms that
12	extrapolate based upon this literature that you have	12	were reported, the actual description of the events
13	just discussed and the congressional information that	13	that were reported in those 57 reports.
14	you discussed, what's the potential erosion adverse	14	Q Okay. And so we know that Jennifer Ramirez
15	events?	15	had her surgery in 2010?
16	A 15,900.	16	A Correct.
17	Q And let's go to sexual dysfunction and walk us	17	Q So if we and this relates to sexual
18	across the chart for that one.	18	dysfunction; right?
19	A There were 57 reports of sexual dysfunction,	19	A Yes.
20	and that would be using the 1 in 100. There would be	20	Q Would that include dyspareunia?
21	potentially 5,700 actual reports of sexual dysfunction.	21	A Yes.
22	Q And if it were 10 in 100, what would it be?	22	Q Would it include the complaints that she
23	A It would be	23	one of the complaints that she is making?
24	Q The next column?	24	A That's correct.
25	A Oh, I'm sorry. You are talking about	25	Q And can we determine from this table and this
	Page 584		Page 586
1	10 percent. Yes.	1	report the number of actual reports that were made from
2	Q Yes.	2	2010 and prior to 2010?
3	A It would be 570.	3	A There were 17 reports of dyspareunia to the
4	Q So the column with 1 percent assumes 1 percent	t 4	MAUDE database prior through 2010.
5	would get reported, and the column with 10 percent on	5	Q Let's just talk about the number of total
6	the far end assumes 10 percent would be reported?	6	reports first.
7	A That's correct.	7	A Oh, I'm sorry.
8	Q Vaginal scarring, walk us across on that one.	8	Q Would it be 57 minus the 33 from 2011?
9	A Vaginal scarring, there were 23 reports.	9	A That's correct.
10	If if 1 in 100 only were reported, there would be	10	Q So would the 24 total dysfunction reports from
11	2300 actual reports.	11	2010 and prior?
12	Q Okay. All right. So and that's Exhibit	12	A Yes.
13	Number?	13	Q And walk us across for example, in 2008
14	A 66.	14	where there were six reports, walk us across that line
15	(The document referenced below was	15	and tell us what that is.
16	marked Deposition Exhibit 67 for	16	A There were six total reports, and in those six
17	identification and is appended hereto.)	17	total reports there were three reports of dyspareunia,
18	BY MR. GOSS:	18	or painful sex, five reports of impaired physical
19	Q Okay. I'm going to hand you what's been	19	relationship, so that there were a total of eight
20	marked as Exhibit 67 and ask you to describe first	20	events reported in those six reports.
21	of all, is Exhibit 67 a slide that you helped assist in	21	Q What's the difference in dyspareunia and
22	preparing?	22	impaired physical relationships?
	A Yes.	23	A The dyspareunia is actual painful sex.
23	11 105.		* *
23	Q And will that assist you in your testimony?	24	Impaired physical relationship means that the the patient is experiencing some impact on the

23 (Pages 583 to 586)

	Page 587		Page 589
1	relationship with their with their partner as a	1	experience with the product once it is on the market.
2	result of what their the sexual dysfunction they are	2	So it includes the complaints that we have been talking
3	experiencing.	3	about, medical device reports, reports in the
4	Q Okay. Then on the right-hand side the only	4	scientific and medical literature. It can also include
5	1 percent reporting, is that, again, based upon the	5	postmarketing studies and assessment of those with the
6	testimony you just gave us relating to a potential of	6	idea being that once the product is on the market and
7	only 1 percent reporting rate in the United States?	7	the product has wide use, the company has the
8	A Yes, that's correct.	8	responsibility to constantly be assessing safety and
9	Q And so if there were a total of 6200 total	9	performance to ensure that there always remains a
10	report I'm sorry, the 6200 potential reports, that	10	favorable benefit-to-risk ratio for use of the device
11	includes from 2004 through 2011?	11	and that the risks are acceptable. And when safety
12	A Yes. And I might clarify that the 6200 is	12	issues arise, or performance issues arise, that that
13	actual events because	13	information is factored back into a risk analysis and
14	Q I got it.	14	appropriate actions are undertaken, such as I mentioned
15	A The 57 is the numbers of patients	15	earlier, changing labeling, doing new studies to better
16	Q Right.	16	understand the safety profile of the product.
17	A which 100 would be 5700 patients, but	17	MR. LEWIS: Objection. Nonresponsive.
18	patients experience multiple events.	18	BY MR. GOSS:
19	Q Okay. If you subtracted the 2011 if you	19	Q Okay. Does the Global Harmonization Task
20	added up just 2004 through 2010 potential reports of	20	Force documents set forth some standards regarding
21	sexual dysfunction, would it be 2800?	21	postmarket surveillance?
22	A Yes.	22	A Yes.
23	Q Okay. Is that something that a reasonable and	23	MR. GOSS: Give me one second, I apologize.
24	prudent manufacturer should consider significant?	24	(The document referenced below was
25	A Yes.	25	marked Deposition Exhibit 68 for
	D F00		
	Page 588		Page 590
1	Q And what with this information, what would	1	identification and is appended hereto.)
1 2		1 2	
	Q And what with this information, what would		identification and is appended hereto.)
2	Q And what with this information, what would a reasonable and prudent manufacturer do?	2	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this
2	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and	2	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been
2 3 4	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning.	2 3 4	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this
2 3 4 5	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in	2 3 4 5	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find
2 3 4 5 6	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66,	2 3 4 5 6	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you
2 3 4 5 6 7	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No.	2 3 4 5 6 7	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization
2 3 4 5 6 7 8	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning?	2 3 4 5 6 7 8	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final
2 3 4 5 6 7 8 9 10	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form.	2 3 4 5 6 7 8	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices.
2 3 4 5 6 7 8 9	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS:	2 3 4 5 6 7 8 9 10 11	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated?
2 3 4 5 6 7 8 9 10 11 12 13	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer	2 3 4 5 6 7 8 9 10 11 12	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006.
2 3 4 5 6 7 8 9 10 11 12 13	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer have done so?	2 3 4 5 6 7 8 9 10 11 12 13	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006. Q And is this a standard does this document
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer have done so? A Yes, definitely.	2 3 4 5 6 7 8 9 10 11 12 13 14 15	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006. Q And is this a standard does this document reflect standards in the industry?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer have done so? A Yes, definitely. Q And was it a violation of the standard of care	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006. Q And is this a standard does this document reflect standards in the industry? A Yes, it does.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer have done so? A Yes, definitely. Q And was it a violation of the standard of care as set forth in the Global Harmonization Task Force	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006. Q And is this a standard does this document reflect standards in the industry? A Yes, it does. Q I'll reference you to page 9 of that document
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer have done so? A Yes, definitely. Q And was it a violation of the standard of care as set forth in the Global Harmonization Task Force documents for Ethicon not to have done so?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006. Q And is this a standard does this document reflect standards in the industry? A Yes, it does. Q I'll reference you to page 9 of that document where it discusses systems for postmarket surveillance.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer have done so? A Yes, definitely. Q And was it a violation of the standard of care as set forth in the Global Harmonization Task Force documents for Ethicon not to have done so? A Absolutely.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006. Q And is this a standard does this document reflect standards in the industry? A Yes, it does. Q I'll reference you to page 9 of that document where it discusses systems for postmarket surveillance. It says 5.1.2.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer have done so? A Yes, definitely. Q And was it a violation of the standard of care as set forth in the Global Harmonization Task Force documents for Ethicon not to have done so? A Absolutely. Q All right. Let's talk a little bit about	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006. Q And is this a standard does this document reflect standards in the industry? A Yes, it does. Q I'll reference you to page 9 of that document where it discusses systems for postmarket surveillance. It says 5.1.2. A Yes.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer have done so? A Yes, definitely. Q And was it a violation of the standard of care as set forth in the Global Harmonization Task Force documents for Ethicon not to have done so? A Absolutely. Q All right. Let's talk a little bit about postmarket surveillance. Explain to the jury what	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006. Q And is this a standard does this document reflect standards in the industry? A Yes, it does. Q I'll reference you to page 9 of that document where it discusses systems for postmarket surveillance. It says 5.1.2. A Yes. Q What is that about? Tell me what that means.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer have done so? A Yes, definitely. Q And was it a violation of the standard of care as set forth in the Global Harmonization Task Force documents for Ethicon not to have done so? A Absolutely. Q All right. Let's talk a little bit about postmarket surveillance. Explain to the jury what postmarket surveillance is.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006. Q And is this a standard does this document reflect standards in the industry? A Yes, it does. Q I'll reference you to page 9 of that document where it discusses systems for postmarket surveillance. It says 5.1.2. A Yes. Q What is that about? Tell me what that means. A This is stating that a medical device
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer have done so? A Yes, definitely. Q And was it a violation of the standard of care as set forth in the Global Harmonization Task Force documents for Ethicon not to have done so? A Absolutely. Q All right. Let's talk a little bit about postmarket surveillance. Explain to the jury what postmarket surveillance is. A Postmarket surveillance encompasses just the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006. Q And is this a standard does this document reflect standards in the industry? A Yes, it does. Q I'll reference you to page 9 of that document where it discusses systems for postmarket surveillance. It says 5.1.2. A Yes. Q What is that about? Tell me what that means. A This is stating that a medical device manufacturer, prior to actually commercializing its
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q And what with this information, what would a reasonable and prudent manufacturer do? A Factor this into the risk analysis and mitigate risk and certainly include it in a warning. Q Did you ever see anywhere where Ethicon considered the information on either Exhibits 67 66, 67, or 65 and did a risk analysis and consider that in connection with the changing of a warning? A No. Q Okay. MR. LEWIS: Objection. Form. BY MR. GOSS: Q Would a reasonable and prudent manufacturer have done so? A Yes, definitely. Q And was it a violation of the standard of care as set forth in the Global Harmonization Task Force documents for Ethicon not to have done so? A Absolutely. Q All right. Let's talk a little bit about postmarket surveillance. Explain to the jury what postmarket surveillance is.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24	identification and is appended hereto.) BY MR. GOSS: Q Dr. Pence I'm going to hand you what's been marked as Deposition Exhibit 68. I actually think this is a document we used last time; I just couldn't find it in the pile of exhibits. And I'm going to ask you what is Exhibit 68? A Exhibit 68 is a guidance document final guidance document produced by the Global Harmonization Task Force entitled Principles of Conformity Assessment for Medical Devices. Q And what is it dated? A June 26th, 2006. Q And is this a standard does this document reflect standards in the industry? A Yes, it does. Q I'll reference you to page 9 of that document where it discusses systems for postmarket surveillance. It says 5.1.2. A Yes. Q What is that about? Tell me what that means. A This is stating that a medical device

24 (Pages 587 to 590)

1	Page 591		Page 593
1	process to assure the continued conformity of the	1	that so I can cure it.
2	device to the essential principles of safety and	2	MR. LEWIS: Foundation. Calls for speculation.
3	performance. And part of the essential principles of	3	MR. GOSS: Okay.
4	safety and performance means that one must all as I	4	BY MR. GOSS:
5	was saying earlier, one must always assure, meaning the	5	Q You can answer the question.
6	company must always assure that there is a favorable	6	A Yes, I did.
7	benefit-to-risk ratio for the device and that risk must	7	Q Okay. And did you review the deposition of
8	be acceptable. And so they must have a system in place	8	Piet Hinoul?
9	to assess the continued conformity of the device to the	9	A Yes, I did.
10	essential principles of safety and performance,	10	Q I'm going to hand you what has previously been
11	basically to ensure that the product continues to have	11	marked in this deposition as Exhibit 40, and this is
12	a favorable benefit-to-risk ratio throughout the	12	what was identified last week as the March 27, 2014,
13	postmarketing phase of the product.	13	deposition I'm sorry, trial proceedings testimony of
14	Q Okay. So, as I understand it, a manufacturer	14	Piet Hinoul in the Linda Batiste trial in Dallas,
15	simply needs to have a system in place to monitor its	15	Texas.
16	products. Is that one thing?	16	Do you recall his testimony in that?
17	A Yes, and that includes what I was discussing a	17	A Yes, I do.
18	little bit earlier, complaint handling, the postmarket	18	Q Is that testimony something that you reviewed
19	vigilance reporting, like the medical device reports	19	in preparation for your opinions?
20	that we were just discussing, and then taking	20	A Yes.
21	appropriate actions based on the findings from	21	Q Do they form the basis of your opinions?
22	postmarket surveillance.	22	A Yes.
23	Q Was that standard in the industry even before	23	Q Okay. I want you to look at page 41, line 13
24	the Global Harmonization Task Force final document carr		through 20, and then lines page 43, lines 6 through
25	out?	25	16. So let's start with 41, lines 13 through 20.
	Page 592	_	Page 594
1	A Yes.	1	Do you see where it picks up with.
2	Q Okay. Let me ask you about that.	2	"Question: Right. And there is"?
3	I mean, as I understand the Global	3	A Correct.
4	Harmonization Task Force document, I mean that was	- 4	Q Okay. I want you to read that excerpt, but
5	were those guidelines typically combining standards in	5	then I want you to also go to page 43, lines 6 through
6	the industry that already existed to try to uniform	6	16, where it picks up with, "Question: Because your
7	make them uniform?	7	
			company"
8	A To harmonize them across the different	8	Do you see that?
9	regions, yes.	9	Do you see that? A Yes.
9 10	regions, yes. Q Was its intent to come up with new standards?	9 10	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit,
9 10 11	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form.	9 10 11	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69?
9 10 11 12	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the	9 10 11 12	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes.
9 10 11 12 13	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that	9 10 11 12 13	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was
9 10 11 12 13 14	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that all the participating parties could agree on the most	9 10 11 12 13 14	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was marked Deposition Exhibit 69 for
9 10 11 12 13 14 15	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that all the participating parties could agree on the most optimal framework from global medical device	9 10 11 12 13 14 15	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was marked Deposition Exhibit 69 for identification and is appended hereto.)
9 10 11 12 13 14 15 16	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that all the participating parties could agree on the most optimal framework from global medical device development.	9 10 11 12 13 14 15	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was marked Deposition Exhibit 69 for identification and is appended hereto.) BY MR. GOSS:
9 10 11 12 13 14 15	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that all the participating parties could agree on the most optimal framework from global medical device development. BY MR. GOSS:	9 10 11 12 13 14 15 16	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was marked Deposition Exhibit 69 for identification and is appended hereto.) BY MR. GOSS: Q Are both those excerpts excerpts that you
9 10 11 12 13 14 15 16 17	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that all the participating parties could agree on the most optimal framework from global medical device development. BY MR. GOSS: Q Let me ask you with respect to Ethicon's	9 10 11 12 13 14 15 16 17	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was marked Deposition Exhibit 69 for identification and is appended hereto.) BY MR. GOSS: Q Are both those excerpts excerpts that you relied upon in forming your opinions?
9 10 11 12 13 14 15 16	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that all the participating parties could agree on the most optimal framework from global medical device development. BY MR. GOSS: Q Let me ask you with respect to Ethicon's conduct in its postmarket surveillance conduct, did you	9 10 11 12 13 14 15 16 17 18	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was marked Deposition Exhibit 69 for identification and is appended hereto.) BY MR. GOSS: Q Are both those excerpts excerpts that you relied upon in forming your opinions? A Yes, that's correct.
9 10 11 12 13 14 15 16 17	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that all the participating parties could agree on the most optimal framework from global medical device development. BY MR. GOSS: Q Let me ask you with respect to Ethicon's conduct in its postmarket surveillance conduct, did you review any testimony in your investigation reflecting	9 10 11 12 13 14 15 16 17	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was marked Deposition Exhibit 69 for identification and is appended hereto.) BY MR. GOSS: Q Are both those excerpts excerpts that you relied upon in forming your opinions? A Yes, that's correct. Q And I'm going to hand you what's been
9 10 11 12 13 14 15 16 17 18 19 20 21	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that all the participating parties could agree on the most optimal framework from global medical device development. BY MR. GOSS: Q Let me ask you with respect to Ethicon's conduct in its postmarket surveillance conduct, did you review any testimony in your investigation reflecting Ethicon's ability to monitor its laser-cut,	9 10 11 12 13 14 15 16 17 18	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was marked Deposition Exhibit 69 for identification and is appended hereto.) BY MR. GOSS: Q Are both those excerpts excerpts that you relied upon in forming your opinions? A Yes, that's correct. Q And I'm going to hand you what's been marked as Deposition Exhibit Number 69. Is that a
9 10 11 12 13 14 15 16 17 18 19 20	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that all the participating parties could agree on the most optimal framework from global medical device development. BY MR. GOSS: Q Let me ask you with respect to Ethicon's conduct in its postmarket surveillance conduct, did you review any testimony in your investigation reflecting Ethicon's ability to monitor its laser-cut, mechanically cut, mesh products?	9 10 11 12 13 14 15 16 17 18 19 20	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was marked Deposition Exhibit 69 for identification and is appended hereto.) BY MR. GOSS: Q Are both those excerpts excerpts that you relied upon in forming your opinions? A Yes, that's correct. Q And I'm going to hand you what's been
9 10 11 12 13 14 15 16 17 18 19 20 21	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that all the participating parties could agree on the most optimal framework from global medical device development. BY MR. GOSS: Q Let me ask you with respect to Ethicon's conduct in its postmarket surveillance conduct, did you review any testimony in your investigation reflecting Ethicon's ability to monitor its laser-cut, mechanically cut, mesh products? A Yes, I did.	9 10 11 12 13 14 15 16 17 18 19 20 21	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was marked Deposition Exhibit 69 for identification and is appended hereto.) BY MR. GOSS: Q Are both those excerpts excerpts that you relied upon in forming your opinions? A Yes, that's correct. Q And I'm going to hand you what's been marked as Deposition Exhibit Number 69. Is that a
9 10 11 12 13 14 15 16 17 18 19 20 21 22	regions, yes. Q Was its intent to come up with new standards? MR. LEWIS: Objection. Form. THE WITNESS: It was basically evaluating the standards that existing existed and ensuring that all the participating parties could agree on the most optimal framework from global medical device development. BY MR. GOSS: Q Let me ask you with respect to Ethicon's conduct in its postmarket surveillance conduct, did you review any testimony in your investigation reflecting Ethicon's ability to monitor its laser-cut, mechanically cut, mesh products?	9 10 11 12 13 14 15 16 17 18 19 20 21 22	Do you see that? A Yes. Q And what's our next slide, 69 next exhibit, 69? THE REPORTER: Yes. (The document referenced below was marked Deposition Exhibit 69 for identification and is appended hereto.) BY MR. GOSS: Q Are both those excerpts excerpts that you relied upon in forming your opinions? A Yes, that's correct. Q And I'm going to hand you what's been marked as Deposition Exhibit Number 69. Is that a slide that you assisted in the preparation of?

25 (Pages 591 to 594)

Page 595 Page 597 1 A Yes. 1 doing testing a variety of ways in which that can be 2 Okay. And does that slide reflect the 2 assessed, and without those mechanisms in place and an 3 3 appropriate investigation, then elucidating, testimony in Pete Hinoul's trial testimony that you 4 4 just reviewed for pages 41, lines 13 through 20, and understanding the safety profile is not possible. 5 43, lines 6 through 16? 5 BY MR. GOSS: 6 6 A Yes. Q And I guess, along those lines, what I really 7 7 Okay. Would you please read that to the jury? Q want to direct you to and for you to direct your 8 8 "Question: Right. And there response to is the standards set forth in the Global 9 9 is a lot of reports that you get Harmonization Task Force documents, the one we just 10 internally from doctors or patients 10 looked at, 5.1.2, regarding systems and safety items saying, 'I've had an erosion' or 'My 11 and monitoring systems in place. Does the testimony 11 12 12 that you just read from Piet Hinoul regarding the patient has had an erosion,' and it 13 turns out that you, your company, 13 ability or inability to track laser-cut mesh or 14 mechanically cut mesh complaints, is that violative of 14 doesn't ever know if it's laser-cut mesh 15 15 or mechanically cut mesh; correct? the Global Harmonization Task Force requirements 16 regarding systems for postmarket surveillance? 16 "Answer: If you don't know the 17 identification number, you wouldn't 17 A Yes. 18 18 know. I agree. Q Okay. Why is that? 19 19 A Because one -- according to the GHTF document "Question: Because your company 20 doesn't necessarily have all of the 20 that we were reading, in order to be able to assess the 21 information from the reports on which it 21 product you have to have postmarket systems in place, 22 22 and there was the mechanically cut mesh product and the is laser-cut or mechanically cut mesh? 23 23 "Answer: Right. laser-cut mesh product and as a result you needed to 24 "Question: You cannot do analysis 24 have a system in place for both to be able to track 25 25 postmarkets and do an appropriate postmarket accurately or say you have done an Page 596 Page 598 analysis accurately to determine whether 1 1 surveillance. 2 or not there's an increase or decrease 2 Q Let's shift gears a little bit. You spoke a 3 of erosions related to laser-cut mesh; 3 little bit last week, you mentioned a registry. Was 4 correct? 4 there a permanent registry -- strike that. 5 5 "Answer: That's right." First of all, what is a registry? 6 Q What's the importance, if any, of what you 6 A A registry is a type of clinical study in 7 7 just read? which patients who are implanted, in this case patients 8 8 A The importance of this is that the company was who would be implanted with the TVT-O, would be 9 9 not evaluating -- in this case it is discussing enrolled and if they consented to be enrolled would be 10 10 erosion, but it would be applicable to other adverse enrolled and followed long-term to determine how the 11 11 events as well, to distinguish the safety profile of product performed and whether -- and what safety issues 12 laser-cut mesh versus the mechanically cut mesh that 12 might arise in the women who participated in the 13 13 was implanted in Ms. Ramirez. registry. It provides -- its key purpose would be to 14 Q Does that violate the Global Harmonization 14 provide long-term safety data. 15 Task Force document you just discussed regarding 15 Q Okay. Tell me, was there ever a permanent 16 postmarket surveillance systems? 16 registry for TVT mesh? 17 17 A Yes. A No. 18 18 Q Why is that? Q Would a reasonable and prudent manufacturer 19 19 MR. LEWIS: Objection. Form. have instituted a permanent registry? THE WITNESS: For example, because we know that 20 20 A A long-term registry, absolutely, yes. 21 from testimony and documentation we have discussed 21 Q Is that part -- appropriate postmarket 22 22 previously that the mechanically cut mesh has a defect surveillance? 23 of fraying and particle loss, and in order to evaluate 23 A That would be, especially for a permanent 24 24 whether or not that has an impact on patient safety, implant, absolutely. 25 one needs to be following that versus laser-cut mesh or Q There's some questions that you received last

26 (Pages 595 to 598)

	Page 599		Page 601
1	week regarding whether there were over 1,000 studies o	1 1	y'all mind taking five minutes?
2	TVT.	2	MR. LEWIS: That's fine.
3	Do you remember that?	3	MS. VERBEEK: Sounds good.
4	A Yes, I do.	4	MR. GOSS: Let me take five minutes, give me a
5	Q The studies that were referenced, do any of	5	chance to go through, and I think we may be within five
6	those distinguish between laser-cut mesh versus	6	minutes of being done.
7	mechanically cut mesh?	7	VIDEO OPERATOR SISSON: 12:47, we are off the
8	A No.	8	record.
9	Q Have you ever seen a study that Ethicon has	9	(Recess taken.)
10	performed to distinguish between laser-cut mesh and	10	VIDEO OPERATOR SISSON: Back at 12:55, we are back
11	mechanically cut mesh?	11	on the record.
12	A Not directed specifically to that question,	12	BY MR. GOSS:
13	no.	13	Q Couple things, Dr. Pence. I think when we
14	Q Were all these studies that are in that big	14	went off the record you had discussed
15	number that's thrown out there, were they all do	15	investigator-initiated studies?
16	they all have safety as their end point?	16	A Yes.
17	A No.	17	Q And you described what that is. Why is it
		18	significant if the study is an investigator-initiated
18	Q What were tell the jury what an end point		study, if at all?
19	is.	19	
20	A The end point is basically what you are	20	A It is different from a company-initiated study
21	evaluating, what you are trying the outcome you are	21	where the company actually monitors it because when a
22	going to evaluate at the end of a clinical study.	22	company conducts a study, a company is required to meet
23	Q So all these this big number that's thrown	23	a certain set of standards, which we call good clinical
24	out of the number of studies, they are not all studying	24	practices, and there are checks and balances in those
25	safety?	25	standards, one of which is that the company is required
	Page 600		Page 602
1	A No. They were much more focused on	1	to monitor the investigation and, for example, the
2	efficacy evaluations.	2	data. The people actually go to the site where the
3	Q What does that mean, "efficacy evaluations"?	3	study is being conducted and they check the data that's
4	A Whether or not the product works and is	4	in the patient record versus the information that's
5	effective for its intended purpose, in this case for	5	being reported and assure that it is accurate and it is
6	stress urinary incontinence.	6	complete, and we know from the literature, for example
7	Q Does an efficacy evaluation evaluate safety?	7	that there is underreporting of safety information in
8	A No.	8	publications, and so there is a different standard that
9	Q Okay. Were some of those studies investigator		is required to be met when a company oversees a produc
10	studies?	10	to ensure that, once again, the data is accurate and
11	A Yes.	11	complete.
12	Q What does that mean?	12	Q So some studies are stronger than others.
13	A Investigator initiated?	13	A Yes.
14	-	14	Q You were asked last week about the number of
15	·	15	
	A Most of them were investigator-initiated	16	cases you have testified in relating to Ethicon. A Yes.
16 17	studies, to the best of my recollection as I sit here	17	
17	today. That means that a physician who is utilizing		Q I think you said a handful or something, I
18	the product implements a study in his patients or	18	don't remember the exact number. Fewer than ten?
1.0	groups with another physician or several physicians to		A Yes.
19	evaluate their patients in a study and report that	20	Q Do you know how many lawsuits are actually
20		~ -	
20 21	data, but it is initiated by the investigator, not the	21	pending in the multi-district litigation against
20 21 22	data, but it is initiated by the investigator, not the company, in this case Ethicon.	22	Ethicon?
20 21 22 23	data, but it is initiated by the investigator, not the company, in this case Ethicon. MR. GOSS: Hey, everyone on the phone, if I can	22 23	Ethicon? A Over 30,000 is my understanding.
20 21 22	data, but it is initiated by the investigator, not the company, in this case Ethicon.	22	Ethicon?

27 (Pages 599 to 602)

	Page 603		Page 605
1	A No, I haven't.	1	longer than what has gone so far. Obviously, I'm going
2	Q Do you know I retained you in Ms. Ramirez's	2	to pass the witness at this point and I'm going to
3	case; right?	3	reserve my I'm not waiving any position that I might
4	A Yes.	4	have in the event that Ethicon is given more time to
5	Q Do you know whether your testimony is going to	5	examine the witness.
6	be used in other cases and potentially spread out among		With that being said, I pass the witness.
7	other cases? Do you know one way or another?	7	MR. LEWIS: Ethicon and Johnson & Johnson will
8	A I don't.	8	reserve their right to ask further questions pending
9	Q Has anybody suggested that to you?	9	the ruling from the court in the hearing that's going
10	A It is my understanding that may be the case,	10	to take place tomorrow on the deposition.
11	yes.	11	MS. VERBEEK: We will reserve for trial.
12	Q Okay. Just to wind this up, we have talked	12	MR. GOSS: Okay. Thank you all for your
13	now for a couple days about your opinions. I started	13	cooperation today.
14	off with these questions, and I'm going to end with	14	THE REPORTER: Who is taking a copy? Mr. Lewis,
15	these questions.	15	you are taking a copy?
16	Have you reached an opinion whether Ethicon	16	MR. LEWIS: That's correct. Do we have a standing
17	violated the standard of care by failing to conduct	17	order?
18	appropriate testing to support the safe and effective	18	THE REPORTER: I believe you do. I just
19	use of the TVT-O the TVT obturator system?	19	MR. LEWIS: Okay.
20	A Yes.	20	THE REPORTER: I probably shouldn't have asked you
21	Q What is that opinion?	21	MR. LEWIS: Yeah, I'll take a copy.
22	A They violated the standard of care and did not	22	THE REPORTER: And, Ms. Verbeek, are you taking a
23	do the appropriate testing.	23	copy?
24	Q Did you reach an opinion whether the labeling	24	MS. VERBEEK: Yes, electronic only.
25	for the TVT obturator system was inadequate?	25	THE REPORTER: Okay. Is everybody taking a rough
	Page 604		Page 606
1	A Yes, I did.	1	draft or nobody taking well, I think defense gets a
2	Q Due to failure to warn?	2	rough draft, plaintiff. And, Ms. Verbeek, do you need
3	A Yes.	3	a rough draft as well?
4	Q And what is that opinion?	4	MS. VERBEEK: No.
5	A The labeling was inadequate.	5	THE REPORTER: And are we expediting?
6	Q Have you reached an opinion as to whether the	6	MR. GOSS: Yes.
7	label was false or misleading?	7	THE REPORTER: Everyone needs an expedite?
8	A Yes.	8	MS. VERBEEK: Yes.
9	Q And what is that opinion?	9	MR. LEWIS: Yes.
10	A The labeling was false and misleading.	10	VIDEO OPERATOR SISSON: At one o'clock, we are of
11	Q Did you reach an opinion as to whether Ethicon	11	the record.
12	failed to meet the postmarket vigilance standard of	12	(The deposition proceeding was adjourned at 1:00 P.M.)
13	care in management of risk?	13	(The deposition proceeding was aujourned at 1.001.WL)
14	A Yes.	14	00000
15		15	
16	Q And what is that opinion? A Ethicon failed to meet the postmarketing	16	
17		17	
18	vigilance standard of care.	18	
	Q And have all the opinions that you have given	19	
19 20	in your deposition been to a reasonable degree of	20	
	scientific and professional certainty?	21	
21 22	A Yes.	22	
23	MR. GOSS: That's all I have.	23	
23	I understand that we have got a hearing tomorrow to determine, among other things, whether this		
25		25	
∠ ⊃	deposition is going to continue for substantially	43	

28 (Pages 603 to 606)

	Page 607		Page 609
1		1	
2		2	ERRATA
3 4	CERTIFICATE OF	3	
5	CERTIFIED SHORTHAND REPORTER	4	PAGE LINE CHANGE
6		5	
7	The undersigned Certified Shorthand Reporter of the State of California does hereby certify:	6	REASON:
8	That the foregoing proceeding was taken before	7	
9	me at the time and place therein set forth, at which time the witness was duly sworn by me;	8	REASON:
,	That the testimony of the witness and all	9	
10	objections made at the time of the examination were	10	REASON:
11	recorded stenographically by me and were thereafter transcribed, said transcript being a true and correct	11	
	copy of my shorthand notes thereof;	12	REASON:
12	That the dismantling of the original transcript will void the reporter's certificate.	13	
13	transcript will void the reporter's certificate.	14	REASON:
14	In witness thereof, I have subscribed my name	15	
15 16	this date:	16	REASON:
17		17	
18 19	PAMELA COTTEN, CSR, RDR	18	REASON:
	Certificate No. 4497	19	
20 21	Certified Realtime Reporter	20	REASON:
22		21	DEAGON
23	(The foregoing certification of	22 23	REASON:
24	this transcript does not apply to any reproduction of the same by any means,	23	DE A SON.
	unless under the direct control and/or	25	REASON:
25	supervision of the certifying reporter.)		
	Page 608		Page 610
1	INSTRUCTIONS TO WITNESS	1	ACKNOWLEDGMENT OF DEPONENT
2		2	I,, do hereby
3	Please read your deposition over carefully and	4	certify that I have read the foregoing pages, and that
4	make any necessary corrections. You should state the	5	the same is a correct transcription of the answers
5	reason in the appropriate space on the errata sheet for	6	given by me to the questions therein propounded, except
6	any corrections that are made.	7	for the corrections or changes in form or substance, if
7	After doing so, please sign the errata sheet	8 9	any, noted in the attached Errata Sheet.
8	and date it.	10	
9 10	You are signing same subject to the changes you have noted on the errata sheet, which will be	11	
11	attached to your deposition.	12	PEGGY PENCE, PhD. (VOLUME II) DATE
12	It is imperative that you return the	13 14	Subscribed and sworn to
13	original errata sheet to the deposing attorney within	11	before me this
14	thirty (30) days of receipt of the deposition	15	
15	transcript by you. If you fail to do so, the		day of,20
16	deposition transcript may be deemed to be accurate an	16 1	
17	may be used in court.	17	My commission expires:
18	•	18	
19			Notary Public
20		19	
21		20	
22			
22 23		20 21	
22		20 21 22	

29 (Pages 607 to 610)